Interference

PATENT
Customer No. 22,852
9960.0001-05

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Keith Campbell et al.	)	Group Art Unit: 1632
	)	
Serial No.: 09/989,128	)	Examiner: D. Crouch
	)	
Filed: November 21, 2001	)	Confirmation No. 1813
	)	

For: UNACTIVATED OOCYTES AS CYTOPLAST RECIPIENTS FOR NUCLEAR TRANSFER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

STATUS INQUIRY

In an Office Communication dated June 3, 2002, the Office indicated that all claims were allowable, but prosecution of the application was suspended due to a potential interference. In an Office Communication dated June 29, 2004, the Office indicated that the outcome of Interference No. 104,746 had a material bearing on the patentability of the claims in this application

Interference No. 104,746 (and Interference Nos. 105,192 and 104,809) has been terminated. Applicants enclose copies of the Decisions and Judgments, together with copies of Notices of Termination of Judicial Review Proceeding, in these Interferences. Please inform applicants of the status of this application.

Respectfully submitted,

Dated: December 20, 2006

By: _____

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Filed on behalf of: Senior Party Campbell
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

STEVEN L. STICE, JOSE CIBELLI, JAMES ROBL,
PAUL GOLUEKE, F. ABEL PONCE de LEON
and D. JOSEPH JERRY,

Junior Party,
(Patent 5,945,577),

v.

KEITH HENRY STOCKMAN CAMPBELL and IAN WILMUT,
Senior Party,
(Application 09/650,194).

Patent Interference 104,746

NOTICE OF TERMINATION OF JUDICAL REVIEW PROCEEDINGS

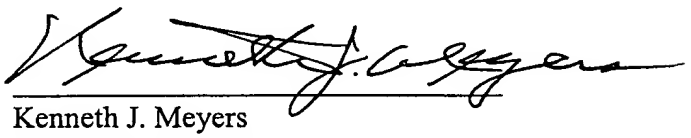
Campbell hereby informs the Board of the termination of proceedings involving judicial review of the Board's Decision on Preliminary Motions dated March 15, 2004, Decision on Priority dated December 20, 2004, and Final Judgment - Priority - Bd. R. 127 dated December 20, 2004, in the United States District Court for the District of Columbia. The appeal proceeding was terminated by entry of a Stipulation of Dismissal filed September 5, 2006, a copy of which is attached hereto.

Also attached is a copy of the Civil Docket for the appeal indicating on page 1 thereof that the case has been "CLOSED. . . ."

Campbell was the Appellee in the District Court proceedings, having received a favorable judgment in the PTO.

A copy of a Settlement Agreement between the parties was filed in the PTO on September 5, 2006.

Respectfully submitted,

Dated: October 12, 2006 By: 

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Counsel of Record for Party Campbell

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing NOTICE OF TERMINATION OF JUDICIAL REVIEW PROCEEDINGS was served on the party STICE through its attorney of record, by Federal Express, on this the 12th day of October, 2006, as follows:

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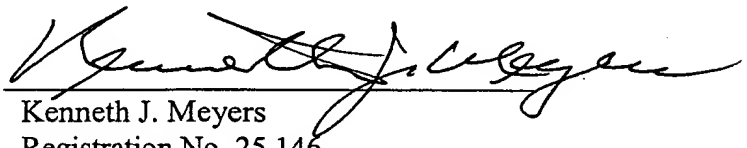
By: 
Kenneth J. Meyers
Registration No. 25,146

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNIVERSITY OF MASSACHUSETTS, et al.	)	
	)	
Plaintiffs,	)	Case No. 1:05-cv-00353 RMU
	)	Judge Ricardo M. Urbina
vs.	)	
	)	
ROSLIN INSTITUTE (EDINBURGH), et al.	)	
	)	
Defendants.	)	

STIPULATION OF DISMISSAL

The parties to the above-captioned action, pursuant to Rule 41(a)(1)(ii), Fed.R.Civ.P., hereby stipulate that this action be dismissed, with prejudice, and without costs.

ROSLIN INSTITUTE (EDINBURGH), GERON CORPORATION, AND EXETER LIFE SCIENCES

By: /s/ Lara C. Kelley

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Attorneys for Defendants

Dated: September 5, 2006

UNIVERSITY OF MASSACHUSETTS AND ADVANCED CELL TECHNOLOGY, INC.

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Attorneys for Plaintiffs

Dated: September 5, 2006

CERTIFICATE OF SERVICE

I hereby certify that on September 5, 2006, a copy of the foregoing **STIPULATION OF DISMISSAL** was filed electronically. Notice of this filing will be sent to the following Attorneys for Geron, et al. by operation of the Court's electronic filing system. Parties may access this filing through the Court's system. A copy of the foregoing and electronic notice of filing will be served on September 5, 2006, upon the following Attorneys for Geron et al. as agreed via e-mail.

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/s/ Frank J. West
Frank J. West

CLOSED, TYPE-E

I. U.S. District Court
District of Columbia (Washington, DC)
CIVIL DOCKET FOR CASE #: 1:05-cv-00353-RMU

UNIVERSITY OF MASSACHUSETTS et al v. ROSLIN INSTITUTE et al
Assigned to: Judge Ricardo M. Urbina
Cause: 35:145 Patent Infringement

Date Filed: 02/18/2005
Jury Demand: None
Nature of Suit: 830 Patent
Jurisdiction: Federal Question

Plaintiff

UNIVERSITY OF MASSACHUSETTS

represented by **Charles L. Gholz**
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V.

Defendant

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Edinburgh

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Defendant

GERON CORPORATION

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Lara C. Kelley
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ATTORNEY TO BE NOTICED

Defendant

EXETER LIFE SCIENCES, INC. represented by **Charles Edmond Lipsey, I**
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LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Lara C. Kelley
(See above for address)
ATTORNEY TO BE NOTICED

II. Date Filed	III. #	IV. Docket Text
02/18/2005	1	COMPLAINT against ROSLIN INSTITUTE, GERON CORPORATION, EXETER LIFE SCIENCES, INC. (Filing fee $ 250) filed by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.(cp,) (Entered: 02/22/2005)
02/18/2005	2	LCvR 7.1 - CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC. (cp,) (Entered: 02/22/2005)
02/22/2005		Summons Issued (3) as to ROSLIN INSTITUTE, GERON CORPORATION, EXETER LIFE SCIENCES, INC.. (cp,) (Entered: 02/22/2005)
03/08/2005	3	Joint MOTION for Extension of Time to *Answer or Otherwise Plead in Response to Complaint* by ROSLIN INSTITUTE, GERON CORPORATION, EXETER LIFE SCIENCES, INC.. (Attachments: # 1 Text of Proposed Order # 2 Certificate of Service)(Kelley, Lara) (Entered: 03/08/2005)
03/09/2005		MINUTE ORDER granting 3 Motion for Extension of Time to file response. Response due 5/2/05 . Signed by Judge Ricardo M. Urbina on 3/9/05. (jp,) (Entered: 03/09/2005)
05/02/2005	4	LCvR 7.1 - CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by EXETER LIFE SCIENCES, INC. (Kelley, Lara) (Entered: 05/02/2005)
05/02/2005	5	LCvR 7.1 - CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by GERON CORPORATION (Kelley, Lara) (Entered: 05/02/2005)
05/02/2005	6	LCvR 7.1 - CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by ROSLIN INSTITUTE (Kelley, Lara) (Entered: 05/02/2005)

05/02/2005	7	ANSWER to Complaint by ROSLIN INSTITUTE, GERON CORPORATION, EXETER LIFE SCIENCES, INC..(Lipsey, Charles) (Entered: 05/02/2005)
05/02/2005		NOTICE of Hearing: An Initial Status Hearing is set for 6/16/2005 at 10:30 AM in Courtroom 12 before Judge Ricardo M. Urbina. Parties are to meed and confer and file their Joint Local 16.3 Report seven (7) days prior to scheduled hearing date.(jwd) (Entered: 05/02/2005)
05/02/2005	8	STANDING ORDER Signed by Judge Ricardo M. Urbina on May 2, 2005. (jwd) (Entered: 05/02/2005)
06/09/2005	9	MEET AND CONFER STATEMENT. (Gholz, Charles) (Entered: 06/09/2005)
06/10/2005	10	Consent MOTION for Leave to Appear Pro Hac Vice *of Frank J. West* by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Affidavit of Frank West Pursuant to Local Rule 83.2(d)# 2 Text of Proposed Order Proposed Order)(Gholz, Charles) (Entered: 06/10/2005)
06/10/2005		MINUTE ORDER granting 10 Motion for Leave to Appear . Signed by Judge Ricardo M. Urbina on 6/10/05. (jp,) (Entered: 06/10/2005)
06/14/2005		MINUTE ORDER. The initial status hearing set for 6/16/05 is vacated. Signed by Judge Ricardo M. Urbina on 6/14/05. (jp,) (Entered: 06/14/2005)
06/15/2005	11	Consent MOTION Regarding Scheduling of Related Cases by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Text of Proposed Order)(Gholz, Charles) (Entered: 06/15/2005)
06/16/2005	12	ORDER Regarding Scheduling of Related Cases Signed by Judge Ricardo M. Urbina on June 16,2005, granting 11 Motion for order regarding scheduling of related cases. (jwd) (Entered: 06/16/2005)
06/16/2005		Set Deadlines/Hearings: Joinder of additional parties/amendment of pleadings 9/30/05. Entry of Protective order/service of initial written discovery by 10/14/2005. Completion of Fact Discovery by 4/14/2006. Service of expert reports by party with burden at trial by 5/3/2006. Service of rebuttal expert report by 6/15/05. Completion of expert discovery by 7/28/2006. Status Conference/Selection of Trial date set for 8/1/2006 at 2:00 p.m. in Courtroom 12 before Judge Ricardo M. Urbina. Dispositive Motions by 8/14/2006; Opposition to Dispositive Motions to be filed 21 days after service of the dispositive motion. Replies in support of Dispositive Motions to be be filed 14 days after service of the oppostion of the dispositive motion. Decision on Dispositive Motions as soon as convenient for the Court but a least

		90 days before trial. Pretrial Conference to be determined. (jwd,) Modified on 6/16/2005 (jwd,). (Entered: 06/16/2005)
06/16/2005		Remark: In the set/reset deadline entry the word Discovery and Rebuttal corrected. (jwd) (Entered: 06/16/2005)
09/06/2005		MINUTE ORDER: The Thursday, September 8, 2005 status conference is VACATED. Signed by Judge Ricardo M. Urbina on 9/6/05. (djr) (Entered: 09/06/2005)
10/14/2005	13	Joint MOTION for Extension of Time to *Enter Protective Order* by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Text of Proposed Order)(Gholz, Charles) (Entered: 10/14/2005)
10/14/2005		MINUTE ORDER: granting 13 the joint motion for extension of time. Upon consideration of the parties' joint motion and for good cause shown therein and as represented in a conference call between both parties' counsel and chambers today, it is hereby ORDERED that the scheduling order dated June 16, 2005, is amended to the extent that the date by which the protective order should be entered is extended until November 14, 2005. SO ORDERED. Signed by Judge Ricardo M. Urbina on 10/14/2005. (Entered: 10/14/2005)
11/01/2005	14	Consent MOTION for Leave to Appear Pro Hac Vice :Attorney Name- Robert H. Stier, Jr.. :Address- Pierce Atwood, LLP, One Monument Square, Portland, ME 04101-1110. Phone No. - 207-791-1163. Fax No. - 207-791-1350 by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Affidavit of Robert H. Stier, Jr.# 2 Text of Proposed Order)(Gholz, Charles) (Entered: 11/01/2005)
11/01/2005		MINUTE ORDER granting 14 Motion for Leave to Appear Pro Hac Vice as to Robert H. Stier. Signed by Judge Ricardo M. Urbina on 11/1/05. (djr) (Entered: 11/01/2005)
11/14/2005	15	Joint MOTION for Protective Order by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Text of Proposed Order)(Gholz, Charles) (Entered: 11/14/2005)
11/15/2005		MINUTE ORDER granting 15 Motion for Protective Order. The Court ENTERS BY REFERENCE the Protective Order attached to the joint motion for protective order. Signed by Judge Ricardo M. Urbina on 11/15/05. (djr) (Entered: 11/15/2005)
03/10/2006	16	MOTION for Discovery *for Entry of Protective Order to Preclude Certain Depositions* by ROSLIN INSTITUTE, GERON CORPORATION, EXETER LIFE SCIENCES, INC.. (Attachments: #

		1 Text of Proposed Order # 2 Exhibit A - Darmouth v. Immunex# 3 Exhibit B - Adhesives Research v. 3M# 4 Exhibit 1 - Stice List of Intended Motions# 5 Exhibit 2 - Order Setting Times# 6 Exhibit 3 - 37 C.F.R. 1.672-673# 7 Exhibit 4 - Excerpts of 9/20/00 Standing Order# 8 Exhibit 5 - Excerpts from 5/1/03 Standing Order# 9 Exhibit 6 - 37 CFR 1.635# 10 Exhibit 7 - 37 CFR 1.687(c)# 11 Exhibit 8 - Plaintiffs' First Doc. Requests# 12 Exhibit 9 - Plaintiffs' First Interrogatories)(Kelley, Lara) (Entered: 03/10/2006)
03/21/2006	17	ENTERED IN ERROR.....Memorandum in opposition to re 16 *Defendants' Motion for a Protective Order* filed by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Exhibit A)(Gholz, Charles) Modified on 3/22/2006 (nmw,). (Entered: 03/21/2006)
03/22/2006		NOTICE OF CORRECTED DOCKET ENTRY: Document No. 17 was entered in error and counsel was instructed to refile said pleading with an active attorney's signature. (nmw,) (Entered: 03/22/2006)
03/22/2006	18	ENTERED IN ERROR.....Memorandum in opposition to re 16 *Defendants' Motion for Protective Order* filed by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Exhibit A)(Gholz, Charles) Modified on 3/23/2006 (nmw,). (Entered: 03/22/2006)
03/23/2006	19	Memorandum in opposition to re 16 *Defendants' Motion for Protective Order* filed by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Exhibit A)(Gholz, Charles) (Entered: 03/23/2006)
03/31/2006	20	REPLY to opposition to motion re 16 MOTION for Discovery *for Entry of Protective Order to Preclude Certain Depositions* filed by ROSLIN INSTITUTE, GERON CORPORATION, EXETER LIFE SCIENCES, INC.. (Kelley, Lara) (Entered: 03/31/2006)
04/10/2006	21	Joint MOTION for Extension of Time to *Complete Fact Discovery* by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Text of Proposed Order)(Gholz, Charles) (Entered: 04/10/2006)
04/11/2006		MINUTE ORDER granting 21 Motion for Extension of Time to complete fact discovery until June 16, 2006. Signed by Judge Ricardo M. Urbina on 4/11/06. (djr) (Entered: 04/11/2006)
04/11/2006		Set Deadlines/Hearings: Discovery due by 6/16/2006. (jwd) (Entered: 04/11/2006)
05/03/2006	22	Joint MOTION for Extension of Time to *Complete Discovery* by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL

		TECHNOLOGY, INC.. (Attachments: # 1 Text of Proposed Order)(Gholz, Charles) (Entered: 05/03/2006)
05/04/2006		MINUTE ORDER granting 22 Motion for Extension of Time. Initial expert reports shall be due by July 7, 2006, rebuttal expert reports shall be due by August 25, 2006, and close of expert discovery shall occur on September 29, 2006. Signed by Judge Ricardo M. Urbina on 5/4/06. (djr) (Entered: 05/04/2006)
05/04/2006		Set Deadlines/Hearings: Expert Discovery due by 9/29/2006. Initial Expert Report due by 7/7/2006. Rebuttal Expert Reports due 8/25/06. (jwd) (Entered: 05/04/2006)
06/05/2006	23	Joint MOTION for Extension of Time to *of Deadlines* by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Text of Proposed Order)(Gholz, Charles) (Entered: 06/05/2006)
06/05/2006		MINUTE ORDER granting 23 Motion for Extension of Time. Fact discovery is due by August 16, 2006, initial expert reports by September 7, 2006, and rebuttal expert reports by October 25, 2006. Expert discovery will close on November 29, 2006 and dispositive motions are due by December 18, 2006. Signed by Judge Ricardo M. Urbina on 6/5/06. (djr) (Entered: 06/05/2006)
06/05/2006		Set Deadlines/Hearings: Fact Discovery due by 8/16/2006. Initial expert reports due by 9/7/2006, and rebuttal expert reports due by 10/25/2006. Expert Discovery will close of 11/29/2006. Dispositive Motions due by 12/18/2006. (jwd) (Entered: 06/05/2006)
06/20/2006	24	ORDER denying 16 Motion for a Protective Order. Signed by Judge Ricardo M. Urbina on 6/20/06. (djr) (Entered: 06/20/2006)
06/20/2006	25	MEMORANDUM AND OPINION. Signed by Judge Ricardo M. Urbina on 6/20/06. (djr) (Entered: 06/20/2006)
07/18/2006		MINUTE ORDER. The August 1, 2006 status hearing is hereby VACATED. The court will consider the parties' dispositive motions, now due December 18, 2006. Signed by Judge Ricardo M. Urbina on 7/18/06. (djr) (Entered: 07/18/2006)
08/01/2006	26	Joint MOTION for Extension of Time to *Meet Deadlines in Court's Scheduling Order* by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Text of Proposed Order)(Gholz, Charles) (Entered: 08/01/2006)
08/02/2006		MINUTE ORDER granting 26 Motion for Extension of Deadlines. The parties shall comply with the following revised schedule: Fact Discovery by 9/15/06; Initial Expert Reports by 10/9/06; Rebuttal

		Expert Reports by 11/20/06; Close of Expert Discovery - 12/29/06; Dispositive Motions by 1/19/07; Oppositions - 21 days thereafter; Replies - 14 days thereafter. Signed by Judge Ricardo M. Urbina on 8/2/06. (djr) (Entered: 08/02/2006)
08/02/2006		Set Deadlines/Hearings: Fact Discovery due by 9/15/2006. Expert Discovery 12/29/2006. Initial Expert Report due by 10/9/2006. Rebuttal Expert Reports 11/20/2006. Dispositive Motions due by 1/19/2007. Opposition 21 days thereafter; replies 14 days thereafter. (jwd) (Entered: 08/02/2006)
09/05/2006	27	STIPULATION of Dismissal by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Gholz, Charles) (Entered: 09/05/2006)

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09/06/2006 10:42:18

PACER Login:	fh0018	**Client Code:**	09960.8053
Description:	Docket Report	**Search Criteria:**	1:05-cv-00353-RMU
Billable Pages:	4	**Cost:**	0.32

Paper No. _____

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES
(Administrative Patent Judge Sally Gardner Lane)

STEVEN L. STICE, JOSE CIBELLI, JAMES ROBL,
PAUL GOLUEKE, F. ABEL PONCE de LEON
and D. JOSEPH JERRY,

Junior Party,
(Patent 6,235,970),

v.

KEITH HENRY STOCKMAN CAMPBELL
and IAN WILMUT,

Senior Party,
(Application 09/989,126).

Patent Interference No. 105,192

NOTICE OF TERMINATION OF JUDICAL REVIEW PROCEEDINGS

Campbell hereby informs the Board of the termination of proceedings involving judicial review of the Board's Decision - Substantive Motions dated February 11, 2005, and Judgment dated February 11, 2005, in the United States District Court for the District of Columbia. The appeal proceeding was terminated by entry of a Stipulation of Dismissal filed September 5, 2006, a copy of which is attached hereto.

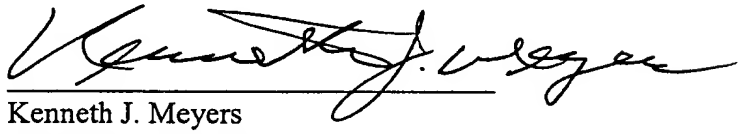
Also attached is a copy of the Civil Docket for the appeal indicating on page 1 thereof that the case has been "CLOSED. . . ."

Campbell was the Appellee in the District Court proceedings, having received a favorable judgment in the PTO.

A copy of a Settlement Agreement between the parties was filed in the PTO on September 6, 2006.

Respectfully submitted,

Dated: October 12, 2006

By: 

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Counsel of Record for Party Campbell

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing NOTICE OF TERMINATION OF JUDICIAL REVIEW PROCEEDINGS was served on the party STICE through its attorney of record, by Federal Express, on this the 12th day of October, 2006, as follows:

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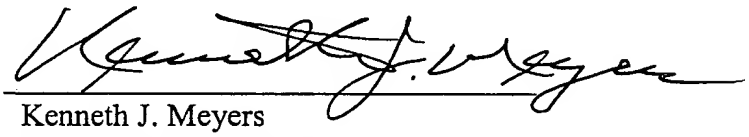
By: 
Kenneth J. Meyers
Registration No. 25,146

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNIVERSITY OF MASSACHUSETTS, et al.	)	
	)	
Plaintiffs,	)	Case No. 1:05-cv-00706 RMU
	)	Judge Ricardo M. Urbina
vs.	)	
	)	
ROSLIN INSTITUTE (EDINBURGH), et al.	)	
	)	
Defendants.	)	

STIPULATION OF DISMISSAL

The parties to the above-captioned action, pursuant to Rule 41(a)(1)(ii), Fed.R.Civ.P., hereby stipulate that this action be dismissed, with prejudice, and without costs.

ROSLIN INSTITUTE (EDINBURGH), GERON CORPORATION, AND EXETER LIFE SCIENCES

By: /s/ Lara C. Kelley

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Attorneys for Defendants

Dated: September 5, 2006

UNIVERSITY OF MASSACHUSETTS AND ADVANCED CELL TECHNOLOGY, INC.

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Dated: September 5, 2006

CERTIFICATE OF SERVICE

I hereby certify that on September 5, 2006, a copy of the foregoing **STIPULATION OF DISMISSAL** was filed electronically. Notice of this filing will be sent to the following Attorneys for Geron, et al. by operation of the Court's electronic filing system. Parties may access this filing through the Court's system. A copy of the foregoing and electronic notice of filing will be served on September 5, 2006, upon the following Attorneys for Geron et al. as agreed via e-mail.

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/s/ Frank J. West
Frank J. West

CLOSED, TYPE-E

I. U.S. District Court
District of Columbia (Washington, DC)
CIVIL DOCKET FOR CASE #: 1:05-cv-00706-RMU

UNIVERSITY OF MASSACHUSETTS et al v. ROSLIN INSTITUTE et al
Assigned to: Judge Ricardo M. Urbina
Cause: 35:146 Patent Interference - Dissatisfaction

Date Filed: 04/07/2005
Jury Demand: None
Nature of Suit: 830 Patent
Jurisdiction: Federal Question

Plaintiff

UNIVERSITY OF MASSACHUSETTS

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Frank J. West
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V.

Defendant

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LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Lara C. Kelley
(See above for address)
ATTORNEY TO BE NOTICED

II. Date Filed	III. #	IV. Docket Text
04/07/2005	1	COMPLAINT against EXETER LIFE SCIENCES, INC., ROSLIN INSTITUTE, GERON CORPORATION (Filing fee $ 250) filed by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC..(jf,) (Entered: 04/08/2005)
04/07/2005		Summons (3) Issued as to EXETER LIFE SCIENCES, INC., ROSLIN INSTITUTE, GERON CORPORATION. (jf,) (Entered: 04/08/2005)
04/07/2005	2	NOTICE OF RELATED CASE by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. Case related to Case No. 05-353. (jf,) (Entered: 04/08/2005)
04/07/2005	3	LCvR 7.1 - CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC. (jf,) (Entered: 04/08/2005)
04/07/2005	4	REPORT on the filing or determination of an action regarding patent and/or trademark number(s) 105,192; 6,235,970. (jeb,) (Entered: 04/11/2005)
04/25/2005	5	Joint MOTION for Extension of Time to *Answer or Otherwise Plead in Response to Complaint* by EXETER LIFE SCIENCES, INC., ROSLIN INSTITUTE, GERON CORPORATION. (Attachments: # 1 Text of Proposed Order)(Kelley, Lara) (Entered: 04/25/2005)
04/27/2005		MINUTE ORDER: granting 5 the parties' joint motion for an extension of time to answer or otherwise plead in response to complaint. Upon consideration of the parties' motion and for good cause shown therein, it is hereby ORDERED that the defendants must answer or otherwise respond to the complaint by no later than June 9, 2005. SO ORDERED. Signed by Judge Ricardo M. Urbina on 4/27/2005. (Entered: 04/27/2005)
04/27/2005		Set Deadlines/Hearings: Answer due by 6/9/2005. (jwd) (Entered: 04/27/2005)
06/09/2005	6	ANSWER to Complaint by EXETER LIFE SCIENCES, INC., ROSLIN INSTITUTE, GERON CORPORATION.(Lipsey, Charles)

		(Entered: 06/09/2005)
06/09/2005	7	LCvR 7.1 - CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by GERON CORPORATION (Kelley, Lara) (Entered: 06/09/2005)
06/09/2005	8	LCvR 7.1 - CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by EXETER LIFE SCIENCES, INC. (Kelley, Lara) (Entered: 06/09/2005)
06/09/2005	9	LCvR 7.1 - CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by ROSLIN INSTITUTE (Kelley, Lara) (Entered: 06/09/2005)
06/09/2005		NOTICE of Hearing:An Initial Status Conference is scheduled for 9/8/2005 at 10:00 AM in Courtroom 12 before Judge Ricardo M. Urbina. Parties are to meet and confer and file their Local Joint 16.3 Report seven (7) days prior to scheduled hearing date.(jwd) (Entered: 06/09/2005)
06/09/2005	10	STANDING ORDER Signed by Judge Ricardo M. Urbina on June 9, 2005. (jwd) (Entered: 06/09/2005)
06/10/2005	11	Consent MOTION for Leave to Appear Pro Hac Vice *of Frank J. West* by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Affidavit of Frank J. West Pursuant to Local Rule 83.2(d)# 2 Text of Proposed Order Proposed Order)(Gholz, Charles) (Entered: 06/10/2005)
06/10/2005		MINUTE ORDER granting 11 Motion for Leave to Appear. Signed by Judge Ricardo M. Urbina on 6/10/05. (jp,) (Entered: 06/10/2005)
06/15/2005	12	Consent MOTION Regarding Scheduling of Related Cases by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Text of Proposed Order)(Gholz, Charles) (Entered: 06/15/2005)
06/16/2005	13	ORDER regarding scheduling of related cases Signed by Judge Ricardo M. Urbina on June 16, 2005, and granting 12 Motion for order regarding scheduling of related cases. (jwd) (Entered: 06/16/2005)
06/16/2005		Set Deadlines/Hearings: Joinder of addtional parties amendment of pladings 9/30/05. Entry of protective order/sercice of initial written discovery by 10/14/2005. Completion of Fact Discovery due by 4/14/2006. Service of expert reports by party with burden at trial by 5/3/06. Service of rebuttal expert Report by 6/15/2005. Completion of expert discovery by 7/28/2006. Status Conference/Secetion of Trial date set for 8/1/2006 at 2:00 p.m. in Courtroom 12 before Judge

		Ricardo M. Urbina. Dispositive Motions to be filed by 8/14/2006; Oppositions to the dispositive Motions to be filed 21 days after service of the dispositive motion. Replies in support of dispositions to be filed 14 days after service of the opposition to the dispositive motion. Decision on the Dispositive Motions as soon as convenient for the Court but at least 90 days before trial. Pretrial Conference to be determined. (jwd) (Entered: 06/16/2005)
09/06/2005		MINUTE ORDER: The Thursday, September 8, 2005 status conference is VACATED. Signed by Judge Ricardo M. Urbina on 9/6/05. (djr) (Entered: 09/06/2005)
10/14/2005	14	Joint MOTION for Extension of Time to *Enter Protective Order* by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Text of Proposed Order)(Gholz, Charles) (Entered: 10/14/2005)
10/14/2005		MINUTE ORDER: granting 14 the joint motion for extension of time. Upon consideration of the parties' joint motion and for good cause shown therein and as represented in a conference call between both parties' counsel and chambers today, it is hereby ORDERED that the scheduling order dated June 16, 2005, is amended to the extent that the date by which the protective order should be entered is extended until November 14, 2005. SO ORDERED. Signed by Judge Ricardo M. Urbina on 10/14/2005. (Entered: 10/14/2005)
11/01/2005	15	Consent MOTION for Leave to Appear Pro Hac Vice :Attorney Name- Robert H. Stier, Jr.. :Address- Pierce Atwood LLP, One Monument Square, Portland, ME 04101-1110. Phone No. - 207-791-1163. Fax No. - 207-791-1350 by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Affidavit of Robert H. Stier, Jr.# 2 Text of Proposed Order)(Gholz, Charles) (Entered: 11/01/2005)
11/01/2005		MINUTE ORDER granting 15 Motion for Leave to Appear Pro Hac Vice as to Robert H. Stier. Signed by Judge Ricardo M. Urbina on 11/01/05. (djr) (Entered: 11/01/2005)
11/14/2005	16	Joint MOTION for Protective Order by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Text of Proposed Order)(Gholz, Charles) (Entered: 11/14/2005)
11/15/2005		MINUTE ORDER granting 16 Motion for Protective Order. The Court ENTERS BY REFERENCE the Protective Order attached to the joint motion for protective order. Signed by Judge Ricardo M. Urbina on 11/15/05. (djr) (Entered: 11/15/2005)

03/10/2006	17	MOTION for Discovery *for Entry of Protective Order to Preclude Certain Depositions* by EXETER LIFE SCIENCES, INC., ROSLIN INSTITUTE, GERON CORPORATION. (Attachments: # 1 Text of Proposed Order # 2 Exhibit A - Dartmouth v. Immunex# 3 Exhibit B - Adhesives Research v. 3M# 4 Exhibit 1 - Stice List of Intended Motions# 5 Exhibit 2- Order Setting Times# 6 Exhibit 3 - 37 CFR 1.672-673# 7 Exhibit 4- Excerpts of 9/20/00 Standing Order# 8 Exhibit 5- Excerpts of 5/1/03 Standing Order# 9 Exhibit 6 - 37 CFR 1.635# 10 Exhibit 7 - 37 CFR 1.687(c)# 11 Exhibit 8 - Plaintiffs' First Doc Requests# 12 Exhibit 9 - Plaintiffs' First Interrogatories)(Kelley, Lara) (Entered: 03/10/2006)
03/21/2006	18	ENTERED IN ERROR.....Memorandum in opposition to re 17 *Defendants' Motion for Protective Order* filed by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Exhibit A)(Gholz, Charles) Modified on 3/22/2006 (nmw,). (Entered: 03/21/2006)
03/22/2006		NOTICE OF CORRECTED DOCKET ENTRY: Document No. 18 was entered in error and counsel was instructed to refile said pleading with an active attorney's signature. (nmw,) (Entered: 03/22/2006)
03/22/2006	19	ENTERED IN ERROR.....Memorandum in opposition to re 17 *Defendants' Motion for Protective Order* filed by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Exhibit A)(Gholz, Charles) Modified on 3/23/2006 (nmw,). (Entered: 03/22/2006)
03/23/2006	20	Memorandum in opposition to re 17 *Defendants' Motion for Protective Order* filed by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Exhibit A)(Gholz, Charles) (Entered: 03/23/2006)
03/31/2006	21	REPLY to opposition to motion re 17 MOTION for Discovery *for Entry of Protective Order to Preclude Certain Depositions* filed by EXETER LIFE SCIENCES, INC., ROSLIN INSTITUTE, GERON CORPORATION. (Kelley, Lara) (Entered: 03/31/2006)
04/10/2006	22	Joint MOTION for Extension of Time to *Complete Fact Discovery* by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Text of Proposed Order)(Gholz, Charles) (Entered: 04/10/2006)
04/13/2006		MINUTE ORDER granting 22 Motion for Extension of Time to complete fact discovery until June 16, 2006. Signed by Judge Ricardo M. Urbina on 4/13/06. (djr) (Entered: 04/13/2006)
04/13/2006		Set Deadlines/Hearings: Discovery due by 6/16/2006. (jwd) (Entered:

		04/13/2006)
05/03/2006	23	Joint MOTION for Extension of Time to *Complete Discovery* by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Text of Proposed Order)(Gholz, Charles) (Entered: 05/03/2006)
05/04/2006		MINUTE ORDER granting 23 Motion for Extension of Time. Initial expert reports shall be due by July 7, 2006, rebuttal expert reports shall be due by August 25, 2006, and close of expert discovery shall occur on September 29, 2006. Signed by Judge Ricardo M. Urbina on 5/4/06. (djr) (Entered: 05/04/2006)
05/04/2006		Set Deadlines/Hearings: Expert Discovery due by 9/29/2006. Initial Expert Report due by 7/7/2006. Rebuttal Expert Report shall be due by 8/25/2006. (jwd) (Entered: 05/04/2006)
06/05/2006	24	Joint MOTION for Extension of Time to *of Deadlines* by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Text of Proposed Order)(Gholz, Charles) (Entered: 06/05/2006)
06/05/2006		MINUTE ORDER granting 23 Motion for Extension of Time. Fact discovery is due by August 16, 2006, initial expert reports by September 7, 2006, and rebuttal expert reports by October 25, 2006. Expert discovery will close on November 29, 2006 and dispositive motions are due by December 18, 2006. Signed by Judge Ricardo M. Urbina on 6/5/06. (djr) (Entered: 06/05/2006)
06/05/2006		Set Deadlines/Hearings: Fact Discovery due by 8/16/2006. Initia expert reports due by 9/7/2006, and rebuttal expert reports due by 10/25/2006. Expert discovery will close on 11/29/2006. Motions due by 12/18/2006. (jwd) (Entered: 06/05/2006)
06/20/2006	25	ORDER denying 17 Motion for a Protective Order. Signed by Judge Ricardo M. Urbina on 6/20/06. (djr) (Entered: 06/20/2006)
06/20/2006	26	MEMORANDUM AND OPINION. Signed by Judge Ricardo M. Urbina on 6/20/06. (djr) (Entered: 06/20/2006)
07/18/2006		MINUTE ORDER. The August 1, 2006 status hearing is hereby VACATED. The court will consider the parties' dispositive motions, now due December 18, 2006. Signed by Judge Ricardo M. Urbina on 7/18/06. (djr) (Entered: 07/18/2006)
07/18/2006		Set/Reset Deadlines: Dispositive Motions due by 12/18/06. (kk) (Entered: 07/18/2006)
08/01/2006	27	Joint MOTION for Extension of Time to *Meet Deadlines in Court's Scheduling Order* by UNIVERSITY OF MASSACHUSETTS,

		ADVANCED CELL TECHNOLOGY, INC.. (Attachments: # 1 Text of Proposed Order)(Gholz, Charles) (Entered: 08/01/2006)
08/02/2006		MINUTE ORDER granting 27 Motion for Extension of Deadlines. The parties shall comply with the following revised schedule: Fact Discovery by 9/15/06; Initial Expert Reports by 10/9/06; Rebuttal Expert Reports by 11/20/06; Close of Expert Discovery - 12/29/06; Dispositive Motions by 1/19/07; Oppositions - 21 days thereafter; Replies - 14 days thereafter. Signed by Judge Ricardo M. Urbina on 8/2/06. (djr) (Entered: 08/02/2006)
08/02/2006		Set Deadlines/Hearings: Fact Discovery due by 9/15/2006. Initial Expert Report due by 10/9/2006. Rebuttal Expert Reports 11/20/2006. Expert Discovery 12/29/2006. Dispositive Motions due by 1/19/2007. Oppositions 21 days thereafter; Replies 14 days thereafter. (jwd) (Entered: 08/02/2006)
09/05/2006	28	STIPULATION of Dismissal by UNIVERSITY OF MASSACHUSETTS, ADVANCED CELL TECHNOLOGY, INC.. (Gholz, Charles) (Entered: 09/05/2006)

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Transaction Receipt

09/06/2006 10:43:59

PACER Login:	fh0018	**Client Code:**	09960.8053
Description:	Docket Report	**Search Criteria:**	1:05-cv-00706-RMU
Billable Pages:	4	**Cost:**	0.32

The opinion in support of the decision being entered today is not binding precedent of the Board.

Paper 93

Filed by: Trial Section Motions Panel
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Filed
11 February 2005

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES
(Administrative Patent Judge Mark Nagumo)

STEVEN L. **STICE**,
JOSE CIBELLI, JAMES ROBL,
PAUL GOLUEKE, F. ABEL PONCE de LEON
and D. JOSEPH JERRY,

Junior Party,
(Patent 6,235,970),

v.

KEITH HENRY STOCKMAN **CAMPBELL**
and IAN WILMUT,

Senior Party,
(Application 09/989,126).

Patent Interference No. 105,192

Before: MCKELVEY, Senior Administrative Patent Judge, and LANE and NAGUMO, Administrative Patent Judges.

NAGUMO, Administrative Patent Judge.

DECISION - SUBSTANTIVE MOTIONS

I. Introduction

This interference relates to methods for culturing certain Inner Cell Mass cells, which are often referred to in the popular press as "embryonic stem cells." The Inner Cell Mass ("ICM") is the cluster of cells in an embryo at the blastocyst (hollow shell) stage that develops into the fetus. Such cells are called "pleuripotent" because they can differentiate to become any tissue in the developing creature. Researchers hope that ways will be found to grow cultured inner cell mass (CICM) cells into tissues useful for diagnosis and therapy of various conditions arising from injury and disease. The particular CICM cells at issue in this interference arise from the implantation of a prepared nucleus from a differentiated cell into a prepared oocyte (egg cell). The process at the core of this interference involves transferring a prepared nucleus into an enucleated oocyte (an egg cell without its own nucleus). When the embryo reaches the blastocyst stage, several days after fertilization, the inner cell mass cells are harvested and cultured in vitro.

An oral hearing was held in the presence of a court reporter on 15 November 2004. (See Paper 91, transcript of oral argument.) Ronald A. Daignault, Esq., accompanied by Joseph M. Bennet-Paris, Esq., argued for Stice. Kenneth J. Meyers, Esq., accompanied by David J. Earp, Esq., argued for Campbell.

II. Findings of fact

The record supports the following findings of fact as well as any other findings of fact set forth in any other portion of the decision by at least a preponderance of the evidence.

The interference

Background

1. This interference was declared on 30 January 2002, between junior party Steven L. Stice, Jose Cibelli, James Robl, Paul Golueke, F. Abel Ponce de Leon, and D. Joseph Jerry ("Stice") and senior party Keith Henry Stockman Campbell and Ian Wilmut ("Campbell").

2. Stice is involved on the basis of U.S. Patent

6,235,970, issued 22 May 2001 ("970 patent"; SX 2002[1]),

which is based on application

08/935,052, filed 22 September 1997

("052 application"),

which was filed as a continuation of US application

08/781,752, filed on 10 January 1997

("752 application"),

which issued as U.S. Patent 5,945,577 on 31 August 1999.

3. Stice has been accorded the benefit for priority of the

[1] Stice exhibits are cited as SX 2___; Campbell exhibits are cited as CX 1___.

752 application. (Paper 1 at 3.)

4. According to Stice, its real party in interest is "the University of Massachusetts, which has exclusively licensed their interest to Advanced Cell Technology Corporation" (Paper 8 at 2).

5. Campbell is involved on the basis of application

09/989,126, filed 21 November 2001 (CX 1009),

as a continuation of

09/650,285, filed 29 August 2000 (now U.S. 6,525,243, issued 25 February 2003; CX 1031), as a continuation of

08/803,165, filed on 19 February 1997 (now U.S. 6,252,133, issued 26 June 2001; CX 1016), as the national stage of

PCT/GB96/02098, filed 30 August 1996 (CX 1013).

The PCT application is based on Great Britain application

GB 9517779.6, filed 31 August 1995 (CX 1010).

6. The specifications of Campbell's United States applications are said to be identical ('126 application, Paper 3a at 1).

7. Campbell has been accorded the benefit for priority with respect to the count of each of the applications cited in paragraph 5. (Paper 1 at 4.)

8. According to Campbell, its real party in interest is

(1) Assignee: Roslin Institute (Edinburgh) of Midlothian, England;

(2) licensees: Geron Corporation, of Menlo Park, CA,

and Exeter Life Sciences, Inc., of Phoenix, AZ.

(Paper 20 at 2.)

9. Terminal disclaimers were filed and accepted in Campbell's involved 126 application against any patent granted on:

application 09/989,128, filed 21 November 2001, (suspended);

application 09/989,125, filed 21 November 2001, (suspended); and U.S. Patent No. 6,252,133.

(126 application Paper 7, filed 11 April 2002.)

The count

10. Count 1, the sole count in this interference, reads:

Claim 1 Stice (6,235,970)

or

claim 20 Campbell (09/989,126).

11. The claims of the parties, all of which correspond to the count, are:

Stice: 1-21

Campbell: 20-36

12. Stice U.S. Patent No. 6,235,970, claim 1, reads:

A method for producing a mammalian cultured inner cell mass (CICM) cell line by nuclear transfer comprising the following steps:

(i) introducing a proliferating differentiated somatic mammalian donor cell or a proliferating differentiated somatic mammalian donor cell nucleus into an enucleated mammalian oocyte of the same species to produce a nuclear transfer unit;

(ii) activating the resultant nuclear transfer unit;

(iii) culturing said activated nuclear transfer unit until at least a size suitable for obtaining ICM cells;

(iv) isolating and culturing ICM cells obtained from said cultured nuclear transfer unit to obtain a cultured inner cell mass (CICM) or CICM cell line.

(Paper 9.)

13. Campbell 09/989,126, claim 20 reads:

A method for producing a mammalian cultured inner cell mass cell by nuclear transfer comprising:

(i) inserting a nucleus of a diploid non-human mammalian differentiated somatic cell in the G1 phase of the cell cycle into an unactivated, enucleated metaphase II-arrested non-human mammalian oocyte of the same species to reconstruct an embryo;

(ii) activating the resultant reconstructed embryo;

(iii) culturing said activated, reconstructed embryo; and

(v) isolating and culturing inner cell mass cells obtained from said cultured activated, reconstructed embryo to obtain a cultured inner cell mass cell.

(Paper 5.)

Preliminary Motions

Stice preliminary motions

14. Stice filed ten preliminary motions.

(1) Stice preliminary motion 1, to add its reissue application [10/833,993] to the interference. (Paper 18.)

(2) Stice preliminary motion 2, contingent on the grant of Stice preliminary motion 1, for benefit for priority of its 052 and 752 applications. (Paper 19.)

(3) Stice preliminary motion 3, to designate Stice claims 12 and 14 as not corresponding to the count. (Paper 31.)

(4) Stice preliminary motion 4, contingent on the grant of Stice preliminary motion 1, to designate Stice Reissue claim 14 as not corresponding to the count. (Paper 32.)

(5) Stice preliminary motion 5, to deny Campbell

benefit of priority of its GB application. (Paper 33.)

(6) Stice preliminary motion 6, to deny Campbell benefit of the Campbell PCT application. (Paper 34.)

(7) Stice preliminary motion 7, to designate Stice claims 19-21 and Campbell claims 31-36 as not corresponding to the count. (Paper 35.)

(8) Stice preliminary motion 8, for judgment that Campbell claims 20-30 are unpatentable under 35 U.S.C. § 112, ¶1, for lack of written description and lack of enablement for cultured inner cell mass cells. (Paper 36.)

(9) Stice preliminary motion 9, for judgment that Campbell claims 20-30 are unpatentable under 35 U.S.C. § 112, ¶2, because the claims allegedly are not drawn to Campbell's invention. (Paper 37.)

(10) Stice preliminary motion 10, contingent on the grant of Stice preliminary motion 1, to designate Stice reissue claims 19-21 and Campbell claims 31-36 as not corresponding to the count. (Paper 38.)

Campbell preliminary motions

15. Campbell filed five preliminary motions.

(1) Campbell preliminary motion 1, for judgment that Stice involved 970 patent lacks an adequate written description

of processes limited to a "proliferating" donor nucleus or cell. (Paper 24.)

(2) Campbell preliminary motion 2, for judgment that Stice involved claims are unpatentable under 35 U.S.C. § 112 ¶¶ 1 and 2, due to the lack of the allegedly critical limitation that the transplanted nuclei "can differentiate." (Paper 25.)

(3) Campbell preliminary motion 3, contingent on the grant of Campbell preliminary motion 2, to add claims to Campbell's involved specification. (Paper 26.)

(4) Campbell preliminary motion 4, contingent on the denial of Campbell preliminary motion 1, to substitute Count 2. (Paper 27.)

(5) Campbell preliminary motion 5, contingent on the grant of Campbell preliminary motion 4, for benefit of the GB application for proposed Count 2. (Paper 28.)

III. Discussion

Campbell Motion 1

16. Campbell seeks judgment that Stice's involved claims 1-21 are unpatentable for lack of an adequate written description of the limitation that the donor cell or nucleus is a proliferating donor cell or nucleus. (Paper 24 at 6.)

17. Stice claim 1 is representative (bold added):

> A method for producing a mammalian cultured inner cell mass (CICM) cell line by nuclear transfer comprising the following steps:
> (i) inserting a **proliferating differentiated somatic mammalian donor cell** or a **proliferating differentiated somatic mammalian donor cell nucleus** into an enucleated mammalian oocyte of the same species to produce a nuclear transfer (NT) unit;
> (ii) activating the resultant nuclear transfer unit;
> (iii) culturing said activated nuclear transfer unit until at least a size suitable for obtaining ICM cells;
> (iv) isolating and culturing ICM cells obtained from said cultured nuclear transfer unit to obtain a cultured inner cell mass (CICM) or CICM cell line.

(The other independent claim, claim 19, contains a similar limitation, viz., "wherein the donor cell is a **proliferating** mammalian differentiated cell or wherein the donor nucleus is from a **proliferating** mammalian differentiated cell." (Paper 9 at 4; bold added).)

18. Neither party disputes that the plain language of the Stice claims indicates that the donor cell or donor cell nucleus must be "proliferating."

19. Campbell urges that the Stice specification does not describe, directly or indirectly, processes that contain this specific limitation:

> Although the '970 patent specification uses the term 'propagating' or 'propagated' in reference to colonies or cultures of cells (CX 1001 at col. 16, lines 33-36 and 56), this term is only used in the context of

> growing populations of cells, which would contain both proliferating and non-proliferating cells. The term is never used in the context of the cell cycle status of a particular cell being used for nuclear transfer as required by Stice's involved claims.

(Paper 24 at 14.)

20. Campbell restates the problem in its reply: "[t]he issue is whether the disclosure of a propagating population of cells, which contains both propagating and non-propagating cells, supports a claim that requires the selection of a single propagating cell from the population." (Campbell reply 1, Paper 64 at 3.)

21. Campbell relies on testimony by Dr. David Wells, Ph.D. ("Wells") (Paper 24 at 4-6 and 15-17).

22. We find that Wells is qualified as an expert witness in the areas of cloning livestock animals, cell cultures, and nuclear transplantation. (CX 1007.)

23. Wells testifies that propagating (proliferating) cells are recognized as being in one of the four stages of the "cell cycle" (G_1, S_1, G_2, M); whereas "quiescent" (living but non-propagating) cells are recognized as being in the "G_0" stage, i.e., as not being in any stage of the cell cycle. (CX 1007 at 2.)

24. Wells testifies further that "[b]ased on my experience using cultured proliferating mammalian differentiated somatic

cells in various stages of the mitotic cell cycle, cell cultures contain cells at various stages of the cell cycle, including cells that are in the G_0 stage and which are therefore not proliferating." (CX 1007 at 3, ¶ 6.)

25. Wells testifies further that the article by Boquest[2] shows that approximately 2.8% of the cells in a cycling (i.e., proliferating) porcine fibroblast cell population were in the G_0 phase of the cell cycle. (CX 1007 at 4, citing CX 1006 at 1016, Table 1.)

26. According to Wells, Boquest reports still higher amounts of G_0 cells in populations of cycling cells that were "grown to confluency." (CX 1007 at 4, citing CX 1006 at 1016, Table 1.)

27. Wells concludes that a propagating culture of fibroblast cells contains both proliferating and quiescent cells. (CX 1007 at 4, ¶ 16.)

28. Campbell urges that Stice's involved specification does not inherently describe transplanting a proliferating cell or a proliferating nucleus into an enucleated oocyte because taking a cell from a proliferating culture does not necessarily result in taking a proliferating cell from that culture. (Paper 24 at 15.)

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[2] A.C. Boquest et al., *Flow cytometric cell cycle analysis of cultured porcine fetal fibroblast cells*, 60 BIOL. REPROD. 1013 (1999) (CX 1006).

29. Stice, in contrast, urges that the "proliferating" limitation is inherent in Example 1 of its involved specification, which describes taking a cell from a clonal fibroblast cell line propagated in a growth medium containing 10% fetal calf serum." (Stice opposition 1, Paper 46 at 8; Stice contingent opposition 1, Paper 47, is moot in view of our denial of Stice preliminary motion 1, *infra*).

30. Stice relies on the testimony of Michael D. West, Ph.D. (Paper 46 at 8-9.)

31. West describes himself as the President, Chief Executive Officer, and Chairman of Advanced Cell Technology, Inc. ("ATC"). (SX 2009 at 2, ¶ 1.)

32. ATC holds an exclusive license to the technology developed by Stice that is involved in this interference. (Fact 4, *supra*.)

33. West has published technical articles in the area of telomerase activity, cell senescence, stem cells and cloning. (SX 2008.)

34. We find that West is qualified to testify as an expert in this interference.

35. West testifies:

> 10. Based on my experience with cell culture, fibroblasts propagated in growth medium containing 10% fetal calf serum and not intentionally grown to very high levels of confluence over an extended period of time would be proliferating, not quiescent.
>
> 11. Based on my experience with cell culture, the propagation of fibroblasts requires splitting and transferring propagating cells into fresh growth medium containing 10% fetal calf serum. The process of diluting and splitting propagating cells during, for example, propagation of colonies of cells from single cells, dilutes out senescent, quiescent and non-propagating cells until the cells have proliferated to the point of senescence.

(SX 2025 at 3.)

36. West quotes from the Stice involved specification,

Example 1:

> Fibroblast cells were plated in tissue culture dishes and cultured in alpha-MEM medium (Bio Whittaker, Walkersville, Md.) supplemented with 10% fetal calf serum (FCS) (Hyclone, Logen, Utah) . . . Each colony was propagated independently of each other . . . One line of cells (CL-1) derived from one colony of bovine embryonic fibroblast cells was used as donor nuclei in the nuclear transfer (NT) procedure.

Column 16, lines 7-11, 49, and 57-59 of the '970 specification.[3]

(SX 2025 at 4, ¶ 12.)

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[3] We find the cited text from Stice Example 1 at column 16, lines 14-18, 56, and 64-66. (SX 2002 at col. 16.)

37. West concludes that "Stice clearly demonstrated use of propagating, synonymous with proliferating fibroblasts for nuclear transfer throughout [the] '970 specification." (SX 2025 at 4, ¶ 14.)

38. Stice does not comment on the Boquest article or on Wells' testimony regarding the Boquest article.

Discussion

Whether claimed subject matter is described by the specification within the meaning of 35 U.S.C. § 112, first paragraph, is a question of fact. *E.g., Noelle v. Lederman,* 355 F.3d 1343, 1348, 69 USPQ2d 1508, 1513 (Fed. Cir. 2004). It is Campbell's burden to come forward with a preponderance of the evidence that the claimed invention is not adequately described. 37 CFR § 41.121(b) (effective 13 September 2004); 37 CFR § 1.637(a) (2003); *Velander v. Garner,* 348 F.3d 1359, 1369-70, 68 USPQ2d 1769, 1777 (Fed. Cir. 2003). A party that seeks to prove that a certain limitation is inherent, however, may not rely on probabilities or possibilities. *In re Robertson,* 169 F.3d 743, 745, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999) ("To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference . . . Inherency, however, may not be established by probabilities or possibilities. The mere

fact that a certain thing may result from a given set of circumstances is not sufficient.") (internal quotes and citations omitted).

The parties agree that the disputed limitation is not expressly present in Stice's involved specification. We find that Campbell, through the testimony of Wells, has established a sound factual basis for doubting that every cell taken from a proliferating cell culture such as described in Stice Example 1 is necessarily a proliferating cell. The weight of the evidence shows that the selected cell may not always be proliferating; in other words, it may be quiescent. Wells' testimony is supported by the Boquest article, which appears to be entirely independent of party Campbell. We find the testimony of West, in support of Stice, to be unpersuasive, as it is essentially conclusory. Not only is West's testimony not supported by an independent publication, but West fails to explain how the procedures described in Stice Example 1 relate to the "process of diluting and splitting propagating cells" that is said to "dilute out" senescent, quiescent, and non-propagating cells from the culture. First, West's statement indicates that non-propagating cells are present to some extent in such cultures, at least initially, thus confirming Campbell's predicate that nonpropagating cells are present in at least some cultures of propagating cells. Moreover

West does not testify that the processes employed in Stice Example 1 invariably and inevitably result in samples that contain no nonpropagating cells. West has failed to explain the underlying technical basis of his opinion, and we do not accord West's testimony significant weight.

We find that a preponderance of the evidence shows that Stice's general descriptions and its specific examples do not amount to an inherent description of processes wherein propagating cells or the nuclei of propagating cells are implanted into enucleated oocytes. Accordingly, Campbell preliminary motion 1 is GRANTED.[4]

Campbell preliminary motion 4, which is contingent on the denial of Campbell preliminary motion 1, is DISMISSED as moot.

Campbell preliminary motion 5, which is effectively contingent on the grant of Campbell preliminary motion 4, is DISMISSED as moot.

Stice motion 3, to designate certain Stice claims as not corresponding to the count is DISMISSED as moot because we have found all of Stice's claims to be unpatentable on grounds unrelated to the basis of Stice motion 3.

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[4] The Board's decision in Interference 104,746 (Paper 80 of that proceeding; CX 1003) is based on a different patent and a distinct record. Therefore, it is not controlling or binding on this panel. We decide each case on its own facts and merits, as it comes before us.

Stice motion 7, to designate certain Stice and Campbell claims as not corresponding to the count is DISMISSED as moot because we have found all of Stice's claims to be unpatentable on grounds unrelated to the basis of Stice motion 7.

Campbell motion 2

Having determined that none of the Stice involved claims are patentable for lack of an adequate written description, we need not consider Campbell preliminary motion 2, that the claims are unpatentable for additional reasons.

Accordingly, Campbell preliminary motion 2 is DISMISSED.

Campbell preliminary motion 3, which is contingent on the grant of Campbell preliminary motion 2, is DISMISSED as moot.

Stice Motion 1

39. Stice preliminary motion 1 seeks to add its reissue application, 10/833,993, filed 28 April 2004, which is based on its involved 970 patent to the interference. (Paper 18.)

40. Specifically, Stice seeks to "replace present claims 1-21 of U.S. Patent 6,235,970 as corresponding to the count of the present interference and that claim 1 of the reissue application as amended corresponds to count 1 of the present interference." (Paper 18 at 2.)

41. Stice states that, in the reissue application, "claims 1, 19, and claim 14 made independent, have been amended to delete the term 'proliferating' and to substitute the term 'propagating.'" (Paper 18 at 3.)

42. Thus, Stice is presenting a reissue application that contains only new claims.

43. Stice has canceled claim 12 of the reissue application. (SX 2001 at 3.)

44. Campbell points out that Stice's reissue claim 1 omits a number of terms, but addressed itself to the substantive issues raised as if the claims contained the missing terms. (Campbell opposition 1, Paper 53 at 1.)

45. Stice, in reply, urges that it has submitted an amendment correcting the omissions. (Stice reply 1, Paper 71 at 2-3.)

46. Review of the official record (i.e., the electronic file) of reissue application 10/833,993, shows that no such amendment was present in the file.

47. Stice preliminary motion 4, which is contingent on the grant of Stice preliminary motion 1, seeks to designate claim 14 of its reissue application as not corresponding to the count. (Paper 32.)

48. Pursuant to a conference call by the Board on December 28, 2004, Stice filed a miscellaneous motion (hereafter, "Stice motion 11") to amend its reissue application 10/833,993 by canceling claim 14 and amending claim 1 to correct inadvertent word-processing errors (Paper 92 (Stice motion 11) and SX 2033 (proposed amendment)).

Discussion

Trial Section precedent interprets Rule 633(h) (July 1, 2004) "to permit the filing of a preliminary motion to add a reissue only if the reissue applicant agrees that all 'new' claims in the reissue application are to be designated as corresponding to the count." *Winter v. Fujita*, 53 USPQ2d 1478, 1483 (Bd. Pat. App. & Int. 2000). Stice preliminary motion 4 indicates that Stice regards claim 14 as not corresponding to the count, but Stice motion 11 removes this obstacle to considering Stice preliminary motion 1.

Ordinarily, an application, including a reissue application will not be placed into an interference unless the claims have been indicated to be allowable by a Primary Examiner.[5] In

[5] *Cf. Brenner v. Manson*, 383 U.S. 519, 528 n.12, 148 USPQ 689, 693 n.12 (1966):

> "[t]here is no basis for the proposition that even where an applicant for an interference presents a claim which on its face is unpatentable, a complicated and frequently lengthy factual inquiry into priority of invention must inexorably take place. On the contrary, Rule 201(a), 37 CFR § 1.201(a), defines an interference proceeding as one involving "two or more parties claiming

extraordinary circumstances, however, it may be appropriate to exercise, on the behalf of the Director of the United States Patent and Trademark Office, discretion to resolve issues efficiently despite procedural irregularities. This is such a case. Accordingly, we GRANT Stice preliminary motion 1 to add reissue application 10/833,993 to this interference.

As a consequence of adding the reissue application, we must consider whether the claims of the reissue application are patentable to Stice. For the following reasons, we conclude that they are not. The differences between claim 1 of the Stice involved 970 patent and proposed reissue claim 1 are the substitutions of the word —propagating— for each occurrence of the word "proliferating" in step (i) of the claimed process. Step (i) of Reissue application claim 1 reads:

> (i) introducing a [proliferating] propagating differentiated somatic mammalian donor cell or a [proliferating] propagating differentiated somatic mammalian donor cell nucleus into an enucleated

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substantially the same patentable invention and may be instituted as soon as it is determined that common patentable subject matter is claimed * * *." (Emphasis supplied.) See *Application of Rogoff*, 46 CCPA 733, 739, 261 F.2d 601, 606, 120 USPQ 185, 188: "The question as to patentability of claims to an applicant must be determined before any question of interference arises and claims otherwise unpatentable to an applicant cannot be allowed merely in order to set up an interference."

mammalian oocyte of the same species to produce a nuclear transfer unit;

in which square brackets indicate text deleted from the patent claim and the underscores indicate text added to the patent claim. (SX 2002 at col. 18 and SX 2033 at 4.) Stice indicated in its principal brief and at oral argument that it regards the terms "propagating" and "proliferating" as having the same meaning. (Paper 18 at 7; Paper 91 at 12, ll. 10-16.) The difference, according to Stice, is that the word "propagating" is present in the Stice specification, whereas "proliferating" is not. (Paper 91 at 12, ll. 16-18.)

We held *supra* in our decision on Campbell motion 1 that the involved Stice specification lacks an adequate written description of the particular subgenus of processes in which the donor cell or the donor cell nucleus is itself "proliferating." On the present record, the description of processes in which a cell is taken from a culture that contains proliferating cells, without more, is not necessarily and inevitably a description of a process in which the selected and transferred cell or nucleus is "proliferating." The reason is that the cell taken from the proliferating culture is not necessarily and inevitably a proliferating cell – it may be a quiescent cell. Merely using the word "propagating," which does occur in the specification,

instead of "proliferating," which does not, does not change the failure of the originally filed specification to describe the invention now claimed.

We therefore find that the claims of Stice's reissue application, as amended, are not patentable to Stice for lack of an adequate written description of the claimed process.

Stice preliminary motions 2, 4, and 10, which are contingent both on the grant of Stice preliminary motion 1 and on the implicit assumption that such claims will be found patentable to Stice, are DISMISSED as moot.[6]

Stice motion 8

Stice preliminary motion 8 seeks, pursuant to 37 CFR § 1.633(a), judgment that Campbell's involved application provides neither an adequate written description nor an enabling disclosure for Campbell's involved claims 20-30. In contrast to Stice motions 5 and 6, Stice bears the burden of showing that Campbell's involved application does not describe or enable the full scope of Campbell's involved claims within the meaning of 35 U.S.C. § 112, first paragraph. Although Stice describes Campbell

[6] Stice reissue claim 14 is related to human embryos because it involves creating a reconstructed human embryo and then producing CICM cell line from the ICM cells of said human embryo. (SX 2001 at 3.) Because we have determined that this claim is not properly before us on other grounds, we need not address the question of whether the USPTO has authority to consider the patentability of this claim. The Consolidated Appropriations Act, 2005, HR4818, Title VI, § 626 reads, "None of the funds appropriated or otherwise made available under this Act may be used to issue patents on claims directed to or encompassing a human organism."

dependent claims 21-30 in its brief (Paper 36 at 19-21, facts 15-24), we discern no separate argument against the patentability of these claims. Accordingly, we restrict our attention to Stice's case for the inadequacy of support for claim 20.

Regarding written description, Stice contends in its principal brief that the Campbell involved 126 specification lacks any description of culturing inner cell mass cells. (Paper 36 at 22.) For the reasons discussed in detail *infra*, we reject this argument as factually incorrect.

Campbell claim 20 reads:

> A method for producing a mammalian cultured inner cell mass cell by nuclear transfer comprising:
> (i) inserting a nucleus of a diploid non-human mammalian differentiated somatic cell in the G1 phase of the cell cycle into an unactivated, enucleated metaphase II-arrested non-human mammalian oocyte of the same species to reconstruct an embryo;
> (ii) activating the resultant reconstructed embryo;
> (iii) culturing said activated, reconstructed embryo; and
> (iv) isolating and culturing inner cell mass cells obtained from said cultured activated, reconstructed embryo to obtain a cultured inner cell mass cell.

Campbell's involved 126 specification contains the following description:

> According to a third aspect of the invention, there is provided a method of preparing an animal, the method comprising:

(a) reconstituting an animal embryo as described above; and
(b) causing an animal to develop to term from the embryo; and
(c) optionally, breeding from the animal so formed.

Step (a) has been described in depth above.

The second step, step (b) in the method of this aspect of the invention is to cause an animal to develop to term from the embryo. This may be done directly or indirectly. . . . In indirect development, however, the embryo may be further manipulated before full development takes place. For example, the embryo may be split and the cells clonally expanded, for the purpose of improving yield.

Alternatively or additionally, it may be possible for increased yields of viable embryos to be achieved by means of the present invention by clonal expansion of donors and/or if use is made of the process of serial (nuclear) transfer. A limitation in the presently achieved rate of blastocyst formation may be due to the fact that a majority of the embryos do not "reprogram" (although an acceptable number do). If this is the case, then the rate may be enhanced as follows. Each embryo that does develop itself can be used as a nuclear donor at the 32-64 cell stage; alternatively, inner cell mass cells can be used at the blastocyst stage. If these embryos do indeed reflect those which have reprogrammed (as seems likely), then each developing embryo may be multiplied in this way by the efficiency of the nuclear transfer process. The degree of enhancement likely to be achieved depends upon the cell type.

(CX 1009 at 15-16 (Campbell involved 126 application); see also CX 1010 at 15-16 (GB application); CX 1013 at 15-16 (PCT application); underscore added.)

We find that Campbell in this passage refers to a process in which an embryo is reconstructed by nuclear transfer into an enucleated oocyte (step (a)). From Campbell's prior description of step (a), we understand (and Stice does not dispute) that Campbell teaches steps (i), (ii), and (iii) of the process covered by claim 20. Regarding step (b), we find that Campbell teaches that the reconstructed embryo may be subjected to indirect development. For example, cells from the embryo may be clonally expanded, "for the purpose of improving yield." Wells testified, "[b]ased on my experience in clonally expanding embryonic cells, in the context of the 126 application, 'clonally expanding' embryonic cells means generating daughter cells by cell division using *in vitro* cell culture of embryonic cells." (CX 1033 at 11-12, ¶ 56.) Thus, we understand from Wells' testimony that clonal expansion of cells involves removing and isolating cells from the embryo and then culturing the cells.

In the first two underscored passages, Campbell teaches generally that daughter cells may be generated by cell division in a culture. In the third underscored passage, Campbell teaches that the source of embryonic cells to be expanded can be ICM cells from the blastocyst stage of the embryo. Such expansion involves culturing the ICM cells. Thus, we find that Campbell provides an adequate description of a process of reconstituting

an embryo by nuclear transplantation comprising steps (i), (ii), (iii), and further, isolating and culturing the ICM cells of the embryo as required by step (iv) of the process recited in Campbell claim 20. In other words, we find that Campbell describes a process in which a reconstructed embryo is created, ICM cells are harvested from the blastocyst stage of the reconstructed embryo, and the ICM cells are then clonally expanded. That description supports Campbell claim 20 within the meaning of 35 U.S.C. § 112, first paragraph.

Stice urges a new theory in its Reply (Paper 78 at 3-4), that Campbell's involved claims lack the allegedly critical limitation that Campbell teaches culturing ICM cells only for the purpose of nuclear transplantation. Stice argues that Campbell is not entitled to broad claim 20, which does not have any use limitations. (Paper 78 at 4.) We dismiss Stice's new ground of argument because it is belated. Stice has not offered any reason that it could not have raised its new thesis in its principal brief. However, even if we were to entertain Stice's new argument, we would reject it to the extent that Stice's rebuttal argument urges that Campbell failed to describe a useful invention commensurate in scope with Campbell claim 20. Stice's reliance on *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 USPQ2d 1498, 1503 (Fed. Cir. 1998), is inapposite,

as Stice has failed to direct our attention to any disclosure in Campbell's 126 specification that indicates that there are no purposes other than nuclear transplantation for which the cultured ICM cells would be useful. Nor has Stice come forward with any probative evidence, e.g., expert testimony or technical articles, that indicate that no uses for such cells were recognized.

As for the alleged lack of enabling disclosure in Campbell's application, Stice argues that "[t]he '126 specification does not disclose any methods for making and using the cultured inner cell mass cells of Claims 20-30." (Paper 36 at 23.) Stice also argues that "Campbell's '126 specification does not disclose any examples, prophetic or working, describing isolation, preparation, and culturing of cultured inner mass cells." (Id.) Stice concludes that it would have required undue experimentation to make and use the cultured inner cell mass cells of claims 20-30. (Id. at 23-34.)

Stice's lack of enablement argument is not persuasive because Stice has not established via expert testimony and citation to relevant scientific and technical literature that one skilled in the art would not have been able to carry out the described embodiment without undue experimentation. Although it was not required to do so, Campbell came forward with evidence

that the culturing of cells, including the culturing of ICM cells, was within the ordinary skill of the art. With regard to enablement, Campbell cites scientific publications and testimony by Wells, indicating that culturing cells, including ICM cells, was a well-established technology prior to the 1995 filing date of the GB application. (Paper 57 at 15-16; Paper 58 at 15-16.) Stice has not put forward any credible evidence to the contrary.

In conclusion, Stice has failed to come forward with sufficient probative evidence to establish that the absence of disclosure in Campbell's involved 126 application would require undue experimentation on the part of the ordinary worker to make and use the claimed invention.

Stice preliminary motion 8 is DENIED.

Stice motions 5 and 6

Stice motion 5 seeks, pursuant to 37 CFR § 1.633(g), to deny Campbell the benefit for priority accorded to Campbell's GB application. (Paper 33 at 2.) Stice motion 6 seeks, pursuant to 37 CFR § 1.633(g), to deny Campbell the benefit for priority accorded to Campbell's PCT application. (Paper 34 at 2.) Stice concedes that the texts of the GB disclosure and the PCT disclosure are substantially the same as the text of Campbell's involved 126 application. (Paper 33 at 11; Paper 34 at 10.) In

both motions 5 and 6, Stice asserts that the benefit of priority requires that the earlier application must provide "an enabling disclosure and written description of the invention claimed in the U.S. application." (Paper 33 at 10; Paper 34 at 10.) Stice urges that Campbell's GB and PCT applications fail in both regards. (*Id.*) Stice, however, limits its arguments to the alleged lack of written description. We have not found any substantive argument directed to the alleged lack of enablement.

In each motion, Stice presents a table which recites, in the first column, the text of Campbell claim 20. The second column of the table recites the support in the PCT and GB ("UK") application allegedly cited by Campbell to the examiner in support of that claim. The third column of the table, which is labeled "Analysis," states that the support recited in column 2 "[d]oes not describe or define what is meant by 'cultured inner cell mass cell.'" (Paper 33 at 11-21; Paper 34 at 10-21.)

Stice next urges that benefit for priority is accorded if the "UK" or PCT application is a constructive reduction to practice, which is satisfied if the application in question satisfies the requirements of 35 U.S.C. § 112, first paragraph, "with at least one embodiment of the count." (Paper 33 at 21 and Paper 34 at 21, each citing *Hunt v. Treppschuh*, 523 F.2d 1386, 1389, 187 USPQ 426, 429 (CCPA 1974).) Stice then urges that:

> [w]e have shown in the previous section that Campbell's [UK/PCT] application does not comply with 35 USC § 112, first paragraph, due to lack of support for Claim 20, designated as the Count. Correspondingly, Campbell's [UK/PCT] application does not fulfill this requirement because it does not provide support within the specification as described herein for the count of a method for producing [a] cultured inner cell mass cell or an inner cell mass cell line, which includes Stice Claim 1 as the other option.

Stice appears to have conflated the requirements for obtaining the benefit for priority in an interference with the requirements for securing the benefits of a prior filing date under 35 U.S.C. §§ 119 and 120. Benefit for priority in an interference is established by demonstrating that a single embodiment within the scope of the count is described and enabled within the meaning of 35 U.S.C. § 112, first paragraph. Such an embodiment, if prior to the earliest benefit date of an opposing party, would preclude, under 35 U.S.C. § 102(g), the grant of a patent to the opposing party. That is, the earlier disclosure would be evidence of prior invention, by another, of the commonly claimed subject matter. Benefit under §§ 119 and 120, however, requires that the entire scope of the claim be both described and enabled. The scope of proof required under §§ 119 and 120 is broader because the benefit precludes the application of art that would otherwise deny patentability of the claimed subject matter.

Stice's arguments are unsatisfactory both procedurally and substantively. Stice fails to make a *prima facie* case that Campbell's specification lacks an adequate written description or an enabling disclosure of the claimed subject matter. Stice's allegations and arguments are not supported by convincing expert testimony that explains what one skilled in the art would understand Campbell's specification to teach. Stice's arguments in its Reply are untimely, as there is no apparent reason why they were not presented in its principal brief.

Substantively, we found in regard to Stice motion 8, *supra*, that the same substantive disclosure in Campbell's involved specification satisfied the heavier burden of written description and enablement of the full scope of the same subject matter. Thus, we readily determine that the lighter burden of description and enablement of a single embodiment within the scope of the count, as defined in the alternative by Campbell claim 20, is fully met.

We conclude that Stice has not carried its burden of proof that Campbell's GB and PCT applications lack a written description or an enabling disclosure of at least one embodiment of a process within the scope of the count. Accordingly, Stice preliminary motions 5 and 6 are DENIED.

Stice preliminary Motion 9

Stice moves for judgment that Campbell claims 20-30 are unpatentable under 35 U.S.C. § 112, second paragraph. (Paper 37 at 2.) Stice urges that Campbell claims 20-30 "do not set forth essential elements of what is regarded by the inventors to be the invention." In Stice's view, the essential elements of Campbell's invention comprise embryos that are "capable of giving rise to a live birth." (Paper 37 at 22, emphasis not reproduced.) At best, the cases cited by Stice support its argument only in *dicta*. Although Stice has cited many excerpts from Campbell's specification, it has not directed our attention to any positive statements that certain intended uses are "essential elements" of the invention. Stice has also failed to identify any statements in the Campbell specification that certain uses, if not recited in a claim, disqualify the invention so defined from being Campbell's invention. Nor has Stice pointed to any such statements in the prosecution history. We decline to hold claims indefinite on the slim predicate Stice infers from its interpretation of Campbell's specification.

Stice urges further that the claims are indefinite in the term "cultured inner cell mass cell," because that term is not defined in Campbell's specification, and it would not have had an apparent meaning based on the prior art. (Paper 37 at 24, citing

the second declaration of Michael D. West ("West 2"), SX 2010.) The argument is belied by West 2 (SX 2010 at 4, ¶ 4), which cites an article, Michelle Sims and N.L. First, *Production of calves by transfer of nuclei from* ***cultured inner cell mass cells***, 90 PROC. NAT'L. ACAD. SCI. USA 6143 (1994) (bold emphasis added). West testified that the knowledgeable person in the art understood distinctions between "non-cultured ICM cells" and "cultured ICM cells." (SX 2010 at 4, ¶ 4.) Thus, we find the factual basis of Stice's argument to be incorrect.

Stice preliminary motion 9 is DENIED.

IV. Order

In view of the foregoing considerations, it is:

ORDERED that Stice preliminary Motion 1 to add reissue application 10/833,993 is GRANTED.

FURTHER ORDERED that Stice Reissue application 10/833,993 is added to this interference.

FURTHER ORDERED that claims 1-11, 13, and 15-21 of Stice Reissue application 10/833,993 are not patentable to Stice under 35 U.S.C. § 112, first paragraph, for lack of written description.

FURTHER ORDERED that Stice preliminary motions 2, 4, and 10, which are contingent on the grant of Stice preliminary

motion 1 and the holding that the claims of Reissue application 10/833,993 are patentable to Stice, are DISMISSED.

FURTHER ORDERED that Stice preliminary 5, 6, and 8 are DENIED.

FURTHER ORDERED that Stice Motions 3 and 7 are DISMISSED.

FURTHER ORDERED that Stice preliminary motion 9 is DENIED.

FURTHER ORDERED that Campbell preliminary motion 1 is GRANTED.

FURTHER ORDERED that Campbell preliminary motions 2, 3, 4, and 5 are DISMISSED as moot.

FURTHER ORDERED that this paper be given an appropriate number and placed in the patent file of U.S. Patent 6,235,970, in the application file of 09/989,126, and in the reissue application file of 10/833,993.

FURTHER ORDERED that if there is a settlement, the attentions of the parties are directed to 35 U.S.C. § 135(c) and 37 CFR § 41.205.

FURTHER ORDERED that attention is directed to the Judgment issued in accompanying Paper 95.

FRED E. McKELVEY Senior Administrative Patent Judge	BOARD OF PATENT APPEALS AND INTERFERENCES
SALLY GARDNER LANE Administrative Patent Judge	
MARK NAGUMO Administrative Patent Judge	TRIAL SECTION MERITS PANEL

Alexandria, VA
11 February 2005

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Paper 94

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Filed
11 February 2005

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES
(Administrative Patent Judge Mark Nagumo)

STEVEN L. **STICE**,
JOSE CIBELLI, JAMES ROBL,
PAUL GOLUEKE, F. ABEL PONCE de LEON
and D. JOSEPH JERRY,

Junior Party,
(Patent 6,235,970 and
Reissue Application 10/833,993)

v.

KEITH HENRY STOCKMAN **CAMPBELL**
and IAN WILMUT,

Senior Party,
(Application 09/989,126).

Patent Interference No. 105,192

Before: MCKELVEY, Senior Administrative Patent Judge, LANE, and NAGUMO, Administrative Patent Judges.

NAGUMO, Administrative Patent Judge.

JUDGMENT

I. Introduction

The following findings of fact are supported by a preponderance of evidence in the record.

1. As a result of the findings of fact and conclusions of law set out in Paper 93 (Decision - substantive motions) of this interference, Stice is not entitled to a patent to any claims of its involved U.S. patent No. 6,235,970.

2. As a result of the findings of fact and conclusions of law set out in Paper 93 (Decision - substantive motions) of this interference, Stice is not entitled to a patent to any claims of Stice reissue application 10/833,993, which is based on the Stice 6,235,970 patent.

III. Discussion

An interference is a proceeding to determine whether or not a patent may be issued to an applicant based on an application, all the claims of which are allowable but for the possibility that another first invented the same subject matter. 35 U.S.C. § 102(g). *Cf. Case v. CPC Int'l, Inc.*, 730 F.2d 745, 750, 221 USPQ 196, 200 (Fed. Cir. 1984) ("[n]o interference in fact means that there is no interfering subject matter, that Case's patent is no impediment to granting CPC the claims of its application.")

Stice is not entitled to any of its patented claims

corresponding to the count: thus, Stice patent 6,235,970 is not an impediment to the issuance of a patent to Campbell based on the 09/989,126 involved application. Similarly, Stice is not entitled to a patent on any of the claims in its reissue application: Thus, the Stice reissue application is not an impediment to the issuance of a patent to Campbell based on the 10/833,993 reissue application. Moreover, Campbell, as the senior party, is presumed to be entitled to the decision on priority.

Under these circumstances, no purpose would be served by proceeding to a priority contest in this interference.

II. Order

In view of the findings of fact and conclusions of law set out in Paper 93 (Decision - substantive motions) of this interference, it is:

ORDERED that Steven L. Stice, Jose Cibelli, James Robl, Paul Golueke, F. Abel Ponce de Leon, and D. Joseph Jerry are not entitled to a patent containing claims 1-21 of U.S. Patent No. 6,235,970.

FURTHER ORDERED that Steven L. Stice, Jose Cibelli, James Robl, Paul Golueke, F. Abel Ponce de Leon, and D. Joseph

Jerry are not entitled to a patent on claims 1-11, 13 and 15-21 of reissue application 10/833,993.

FURTHER ORDERED that this judgment is final for purposes of appeal regarding the status of Stice's 6,235,970 patent.

FURTHER ORDERED that this paper be given an appropriate number and placed in the patent file of U.S. Patent 6,235,970, in the application file of 09/989,126, and in the reissue application file of 10/833,993.

FURTHER ORDERED that the reissue application is returned to the jurisdiction of the primary examiner for action not inconsistent with this decision.

FURTHER ORDERED that the attention of Campbell and the primary examiner is directed to related cases 09/989,178 and 09/989,125, both currently suspended;

FURTHER ORDERED that if there is a settlement, the attentions of the parties are directed to 35 U.S.C. § 135(c) and 37 CFR § 41.205.

FRED E. McKELVEY Senior Administrative Patent Judge	BOARD OF PATENT APPEALS AND INTERFERENCES
SALLY GARDNER LANE Administrative Patent Judge	
MARK NAGUMO Administrative Patent Judge	TRIAL SECTION MERITS PANEL

Alexandria, VA
11 February 2005

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Paper 123

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Filed
20 December 2004

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES
(Administrative Patent Judge Nagumo)

STEVEN L. **STICE**,
JOSE CIBELLI, JAMES ROBL, PAUL GOLUEKE,
F. ABEL PONCE de LEON,
and D. JOSEPH JERRY,

Junior Party,
(Patent 5,945,577),

v.

KEITH HENRY STOCKMAN **CAMPBELL**
and IAN WILMUT,

Senior Party,
(Application 09/650,194).

Patent Interference No. **104,746**

Before: McKELVEY, Senior Administrative Patent Judge, LANE, and NAGUMO, Administrative Patent Judges.

NAGUMO, Administrative Patent Judge.

DECISION ON PRIORITY

I. Introduction

This interference relates to methods for cloning certain large farm animals, namely cattle, sheep, and pigs, by transferring the nucleus of a differentiated cell (a fibroblast) into a prepared oocyte at a specified stage of development. A merits panel held that junior party Stice was not entitled to a patent on any of its involved claims, which were claims 1-24 of its U.S. patent No. 5,945,577. (Paper 80 at 37-40.) The interference was redeclared with three counts, Counts 4 through 6, based solely on certain surviving claims of senior party Campbell. (Paper 81 at 3.)

An oral hearing on priority was held in the presence of a court reporter on 15 November 2005. (See Paper 120, transcript of oral argument.) Ronald A. Daignault, Esq., argued for Stice. Kenneth J. Meyers, Esq., accompanied by David J. Earp, Esq., argued for Campbell.

II. Findings of fact

The record supports the following findings of fact as well as any other findings of fact set forth in any other portion of the decision by at least a preponderance of the evidence.

The interference

1. This interference was declared on 30 January 2002, between junior party Steven L. Stice, Jose Cibelli, James Robl, Paul Golueke, F. Abel Ponce de Leon, and D. Joseph Jerry ("Stice") and senior party Keith Henry Stockman Campbell and Ian Wilmut ("Campbell").

2. Stice is involved in the interference on the basis of its 5,945,577 ("577") patent, issued on 31 August 1999, and based on application 08/781,752, filed 10 January 1997.

3. According to Stice, its real party in interest is "the University of Massachusetts, which has exclusively licensed their interest to Advanced Cell Technology Corporation" (Paper 9).

4. Campbell is involved in the interference on the basis of its 09/650,194 ("194") application, filed 29 August 2000.

5. According to Campbell, its real party in interest is

(1) Assignee: Roslin Institute (Edinburgh) of Midlothian, England;

(2) licensees: Geron Corporation, of Menlo Park, CA, and Exeter Life Sciences, Inc., of Phoenix, AZ. (Paper 98 at 2.)

The counts

6. **Count 4** reads as follows (Paper 81 at 3):

A method according to any of claims 19 or 23 of Campbell application 09/650,194.

7. **Count 5** reads as follows (Paper 81 at 3):

A method according to any of claims 27 or 31 of Campbell application 09/650,194.

8. **Count 6** reads as follows (Paper 81 at 3):

A method according to claim 35, claim 39, claim 43 or claim 47 of Campbell application 09/650,194, where the "non-human mammal" is a pig or a porcine and where the "non-human mammalian fetus" is a pig fetus or a porcine fetus.

9. Claim 23 of Campbell reads as follows:

A method of cloning a bovine fetus by nuclear transfer comprising:

(i) inserting a nucleus of a cultured diploid bovine fibroblast in the G1 phase of the cell cycle into an unactivated, enucleated metaphase II-arrested bovine oocyte to reconstruct an embryo;

(ii) maintaining the reconstructed embryo without activation for a sufficient time to allow the reconstructed embryo to become capable of developing to term;

(iii) activating the resultant reconstructed embryo;

(iv) culturing said activated, reconstructed embryo to blastocyst; and

(v) transferring said cultured, reconstructed embryo to a host cow such that the reconstructed embryo develops into a fetus.

10. The other Campbell claims referred to in the counts are independent claims that are also directed to methods of cloning by nuclear transfer comprising the same overall steps as Campbell claim 23. The following differences are noted:

(a) Campbell claim 19 is directed to a method of cloning a cow.

(b) Campbell claim 27 is directed to a method of cloning a sheep.

(c) Campbell claim 31 is directed to a method of cloning an ovine fetus.

(d) Campbell claim 35 is directed to a method of cloning a non-human mammal.

(e) Campbell claim 39 is directed to a method of cloning a non-human mammalian fetus.

(f) Campbell claim 43 is directed to a method of cloning a non-human mammal and requires that the donor cell be a differentiated cell.

(g) Campbell claim 47 is directed to a method of cloning a non-human mammalian fetus and requires that the donor cell be a differentiated cell.

Claim correspondence

11. The claim correspondence was not disturbed by the redeclaration of this interference. (Paper 83.)

a. The claims corresponding to **Count 4** are:

Stice: 1-24

Campbell: 19-26 and 35-50

b. The claims corresponding to **Count 5** are:

Stice: 1-22

Campbell: 27-50

c. The claims corresponding to **Count 6** are:

Stice: 1-22

Campbell: 35-51[1].

[1] Campbell was authorized to file an amendment adding claim 51 to its involved application (Paper 32 at 2). Campbell claim 51 is directed to a method of cloning a pig using the nuclear transfer method and thus corresponds to Count 6.

12. No Stice claims are patentable. (Paper 80 at 40, 43.)

Benefit

13. Stice was not accorded priority benefit of the filing date of any prior application (Paper 81 at 3).

14. Campbell was accorded priority benefit of the following three applications for all three counts of the interference (Paper 81 at 3):

US application 08/803,165, filed 19 February 1997, and issued as patent 6,252,133 on 26 June 2001;

PCT application PCT/GB96/02098, filed 30 August 1996; and

GB application 9517779.6, filed 31 August 1995.

15. The parties continue to rely on their original priority statements. (Paper 83 (Campbell); Paper 84 (Stice).)

Arguments

16. Stice filed a principal brief on priority (Paper 92), which Campbell opposed (Paper 104); Stice filed a reply (Paper 106).

17. Stice subsequently filed a corrected brief (Paper 115) pursuant to an Order (Paper 112) to renumber its exhibits consecutively.

18. Campbell filed a principal brief on priority (Paper 99), which Stice did not oppose, as Campbell noted in a "Notice concerning filing of reply brief" (Paper 107).

Stice case for priority

Conception

19. Stice points to an entry dated "6/22/95" in a laboratory notebook prepared by Dr. Steven L. Stice as evidence of conception. (Paper 115 at 8.)

20. According to Stice, the critical sentence supporting conception reads:

"Want to try electroporation on fibroblast so that they can be used to produce nuclear transfer embryos from clonal cells. Will talk to Jose [Cibelli] about this."

(Paper 115 at 8, citing SX 2055[2].)

21. Stice represents that Dr. Stice signed this page of his laboratory notebook on 23 June 1995. (Paper 115 at 8.)

22. Stice represents further that this page was "subsequently corroborated" by Mr. Jeffrey Kane on 30 April 1997.

23. Review of Stice exhibit SX 2055 (Stice notebook) confirms the dates cited by Stice.

24. Exhibit 2055 is not labeled by any page numbers.

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[2] Stice Exhibits are cited as SX 2___; Campbell exhibits are cited as CX 1___.

25. Kane testified that he signed the notebook on the date indicated. (SX 2052 at 1.)

26. Stice argues that "this is the first date [22 June 1995] indicating the conception by Dr. Steven Stice of a method of using differentiated donor cells (i.e. fibroblast cells) as donor cells for subsequent nuclear transfer experiment from which offspring could be generated. The conception corresponds to the subject matter of the Counts." (Paper 115 at 8-9.)

27. Stice has not, in its principal brief, directed our attention to any expert testimony or other evidence supporting its assertions regarding the critical sentence and its relation to any of counts 4-6.

28. Dr. Stice testified, "[t]hat entry [SX 2055] indicates that I wanted to try the process of electroporation on fibroblst cells in order that they may be used to produce nuclear transfer embryos from the cloned cells. I also indicated in my notebook that I wanted to talk to my colleague, Dr. Jose Cibelli, regarding developing this technology." (Stice declaration, SX 2050 at 2-3.)

29. We find no explanation in Stice's declaration of the relation of his sentence to the limitations of any of the Counts.

30. According to Stice, on another page of Dr. Stice's laboratory notebook, in an entry dated 27 June 1995, Dr. Stice

wrote, "Try to use the electroporation to introduce β-geo into fibroblast cells bovine (Jose's [Cibelli]). The idea is to use these transgenic cells in NT [nuclear transfer] to produce fetuses and offspring? machine?" (SX 2056; square-bracketed material added by Stice.)

31. Exhibit 2056 is not labeled by any page numbers.

32. Review of SX 2056 indicates that Dr. Stice wrote "Tried", rather than "Try" in the sentence quoted by Stice.

33. Dr. Stice appears to have signed and dated this page on 28 June 1995. (SX 2056.)

34. Exhibit 2056 also shows a partial signature, "Jeffrey J. Ka", and a partial date, "April 30". (SX 2056.)

35. Kane testified that he reviewed and signed the pages of the laboratory notebooks shown in SX 2055 and SX 2056 in 1997. (SX 2052 at 1, ¶2.)

36. Stice offers, as collaboration of Dr. Stice's conception, the signature and declaration of Mr. Jeffrey Kane (SX 2052). (Paper 115 at 8.)

Reduction to practice

37. Stice provides a "summary" of Cibelli's research notebooks (SX 2057 and 2058) covering the period 10 August 1995 through 30 August 1996. (Paper 115 at 10-21.)

38. Stice urges that it achieved an actual reduction to practice of subject matter within the scope of Count 4 on or about 30 August 1996, as shown by an entry in a notebook maintained by Cibelli. (Paper 115 at 21.)

39. Stice characterizes the actual reduction to practice as one in which "successful nuclear transfer fusions using differentiated fibroblast cells were completed leading to viable offsprings." (Paper 115 at 21.)

40. The summary for activities of 30 August 1996 refers to pregnancies of "7/30/96." (Paper 115 at 20.)

41. There is no entry in the summary table for 30 July 1996.

42. Stice, in its principal brief, has not directed our attention to any expert testimony that explains any of the summaries of Cibelli's notebooks, nor how the summaries relate to any of the counts in this interference.

43. Stice, in its principal brief, has not made any arguments relating the evidence on which it ultimately relies to support its actual reduction to practice, namely Cibelli's notebooks, SX 2057 and SX 2058, to the limitations of any of the counts.

44. Stice, in its principal brief, has not directed our attention to any expert testimony explaining the significance of

any entries in Cibelli's notebooks vis-à-vis any count; nor are any of the data in the notebook explained as to their origin, meaning, or reliability.

Diligence

45. Campbell has been accorded the benefit for priority in this interference of its UK application, filed on 31 August 1995. (Paper 81 at 3)

46. Stice cites a second entry from Dr. Stice's notebook as evidence of the beginnings of a "concerted effort to reduce this invention to practice: "Try [sic: Tried] to use the electroporation to introduce β-geo into fibroblast cells bovine (Jose's). The idea is to use these transgenic cells in NT to produce fetuses and offspring? machine?"). (Paper 92 at 10, square bracketed remarks added by Stice omitted.)

47. Stice provides a table that begins at page 10 of its priority brief and runs to the top of page 21, in which dates are paired against brief descriptions of activity, which are said to be summaries of notebook pages from Dr. Jose Cibelli's laboratory notebook.

48. Stice, in its principal brief, has not directed our attention to any testimony explaining the meaning or significance of any entries in the table.

49. The entries in the table are dated from 10 August 1995 through 30 August 1996.

50. Stice's table starts 22 days before Campbell's priority benefit date of 31 August 1995.

51. Stice's table indicates activity on 10 of the 22 days before 31 August 1995.

52. The 12 days of inactivity between the start of the Stice Table and 31 August 1995 comprise four blocks of three days each.

53. Stice has not offered any explanation of these periods of silence.

54. Of the 365 days covered by Stice's table following 31 August 1995, 149 are days for which some activity was reported. and 216 are days without reports of activity.

55. From a calendar marked up to indicated the days of activity chronicled in Stice's table, it is apparent that there are several larger blocks of time after Campbell's priority benefit date during which no activity was reported..

a. The largest block of unexplained inactivity extends 18 days, from 29 June 1996 through 16 July 1996.

b. The second largest block of unexplained inactivity covers 16 days, from 4 November 1995 through 19 November 1995.

c. The remaining periods of unexplained inactivity after 31 August 1995 are all of shorter duration – there are three seven-day periods, three six-day periods, and six five-day periods of unexplained inactivity; we have not counted the number of shorter periods of inactivity following 31 August 1995.

d. The sum of these shorter periods of inactivity is 223 days.

56. Stice, in its principal brief, has neither identified nor explained any gaps of activity during the period covered by the table.

57. Stice, in its principal brief, has not described any activities from the period 30 August 1996 through 10 January 1997, the filing date of the application that resulted in its involved patent.

a. This last period of unexplained inactivity covers 133 days.

58. Stice offers, as corroboration of its actual reduction to practice and diligence, the signature of Ms. Catherine Blackwell ("Blackwell") on Cibelli's notebook pages presented in SX 2057, and her declaration.

59. Blackwell declares, "[b]eginning during the period of approximately June 1995, I was aware of a research project conducted primarily by Drs. Stice and Cibelli regarding the issue

of differentiated cells in nuclear transfer technology. Their goal was to produce embryos from the cloned differentiated cells." (SX 2053 at 2, ¶ 2; SX 2054 at 2, ¶2.)

Cibelli's notebooks

60. Dr. Jose B. Cibelli ("Cibelli") states, "[w]hile affiliated with Advanced Cellular Technology, my colleague and I, Dr. Steven Stice, began a series of experiments on or about June 1995 and continuing through the end of 1996, using nuclear transfer techniques with differentiated cells in the hopes of developing a method for produced cloned animals." (SX 2051 at 2, ¶ 3.)

61. Copies of Cibelli's notebook pages are presented in SX 2057 and SX 2058.

62. SX 2058 consists of two parts.

63. Part one of SX 2058 consists of pages 1 (cover) through 59 of a 96-page bound notebook, with dated entries running from "8/10/95" through "2/5/96".

64. Page numbers 2 through 59 of SX 2058 are handwritten entries at the bottom center of each page; the cover of the first notebook is not numbered.

65. Pages 1-59 of SX 2058 are not signed by the writer.

66. Pages 1-59 of SX 2058 are not witnessed, i.e., signed and dated by another, signifying that the pages have been read and understood.

67. Page 59 of SX 2058 has the notations "END OF BOOK", what appears to be signature of Jose Cibelli, and "NEXT BOOK ACT#9".

68. Part two of SX 2058 appears to consist of the cover of "NOTEBOOK NO. 9" and pages 1-80 (so labeled, apparently by the manufacturer) of that notebook.

69. Page 60 of SX 2058 appears to be the cover of "Notebook No. 9," issued to Jose Cibelli, Department ACT, returned 7 August 1997.

70. Page numbers, "60" through "141", have been entered by hand at the bottom center of each page of part two of SX 2058.

71. Pages 60-141 of SX 2058 appear generally to have been signed by Jose Cibelli on the last date noted on the body of each page.

72. Pages 61-141 appear to have been witnessed (signature illegible) in blocks at intervals of a few weeks.

73. The first entry is dated "2/5/96" and witnessed "2-9-96".

74. The last entry is dated "7/26/96" and witnessed "7-30-96".

75. SX 2057 (corrected) covers pages 81 to 102 (pre-numbered), 26 July 1996, through 4 September 1996, of a notebook, which appears to be the continuation of "Notebook No. 9".

76. Pages 81-102 are signed and dated as in SX 2058, "Notebook No. 9".

77. Page 81 is dated "7/26/96". (SX 2057).

78. Page 102 is dated "9/4/96". (SX 2057).

79. Pages 81-102 also bear the witness signature of Catherine E. Blackwell and the witness date of "5/8/97". (SX 2057).

Campbell case for priority

80. Campbell rests its case for priority on its British Application No. GB 95 17779.6 (CX 1003), filed 31 August 1995, the benefit for priority of which it has been accorded. (Campbell Principal Brief on Priority, Paper 99 at 2.)

81. Stice has not filed a brief in opposition to Campbell's case in chief for priority.

III. Discussion

The senior party in an interference is presumed to be the first inventor. 37 CFR § 41.207(a)(1) (2004)[3]. The junior party

[3] New regulations governing interferences before the United States Patent and Trademark Office were published at 69 Fed. Reg. 49,960 (12 August 2004), effective 13 September 2004. Except in those instances in which a party would be

bears the burden of proving, by a preponderance of the evidence, a prima facie case that it was the prior inventor. The party filing a motion has the burden of proof to establish that it is entitled to the requested relief. 37 CFR § 41.121(b) (2004); *Velander v. Garner*, 348 F.3d 1359, 1369-70, 68 USPQ2d 1769, 1777 (Fed. Cir. 2003). As a consequence, if the junior party fails to make out a prima facie case that it was the prior inventor, the senior party is awarded judgment by default.

A party who was not the first to file an application for patent of the interfering invention may nonetheless be adjudged the first inventor if it proves that it was the first to conceive of an embodiment of the interfering invention, and that it worked diligently to reduce an embodiment of the interfering invention to practice from a time before the senior party conceived of its invention until the junior party reduced its invention to practice. "Priority and its constituent issues of conception and reduction to practice are questions of law predicated on subsidiary factual findings." *Eaton v. Evans*, 204 F.3d 1094, 1097, 53 USPQ2d 1696, 1698 (Fed. Cir. 2000).

Conception

Conception is the formation "in the mind of the inventor of a definite and permanent idea of the complete and operative

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prejudiced due to a reliance on the old rules, the new rules shall be applied.

invention, as it is therefore to be applied in practice." *Kridl v. McCormick*, 105 F.3d 1446, 1449, 41 USPQ2d 1686, 1689 (Fed. Cir. 1997) (citations omitted). Conception must include every feature or limitation of the claimed invention. *Id.* Moreover, "[c]onception must be proved by corroborating evidence . . . a reasonable analysis of all the pertinent evidence to determine whether the inventor's testimony is credible. The tribunal must also keep in mind the purpose of corroboration, which is to prevent fraud, by providing independent confirmation of the inventor's testimony.") *Id.* at 1449-50, 41 USPQ2d at 1689; (citations omitted.) Nonetheless, the sufficiency of corroborative evidence must be judged by the 'rule of reason,' under which the tribunal must consider and analyze all pertinent evidence to determine whether the inventor's testimony is credible. *Id.* As the Federal Circuit has emphasized, "Because conception is a mental act, evidence of conception must ultimately address whether the inventor formed 'the definite and permanent idea of the complete and operative invention' in his or her mind." *In re Jolley*, 308 F.3d 1317, 1325, 64 USPQ2d 1901, 1907 (Fed. Cir. 2002).

In the present case, with respect to count 4, junior party Stice seeks to show that it was the first to conceive and that it acted diligently to reduce its invention to practice from a time

before senior party Campbell conceived of its invention. Stice's arguments fail at virtually every level.

First, Stice has failed to show that its evidence of conception, when read by one skilled in the relevant art, discloses every element of the count. The alternative definition of count 4 provided by Campbell claim 23, which recites a method of cloning a bovine fetus, is the most relevant to Stice's proofs. The limitation to which the parties have devoted the most attention is underscored in the first step, which reads as follows:

> (i) inserting a nucleus of a cultured diploid bovine fibroblast <u>in the G1 phase of the cell cycle</u> into an unactivated, enucleated metaphase II-arrested bovine oocyte to reconstruct an embryo.

The evidence on which Stice relies for its proof of conception is directed to fibroblasts generally: "Want to try electroporation on fibroblast so that they can be used to produce nuclear transfer embryos from clonal cells. Will talk to Jose about this." (SX 2055.) This statement, by itself, does not relate to cattle in particular, as recited in Campbell claim 23. As counsel for Stice conceded at oral argument, "there is no cow there." (Paper 120 at 10, l. 12 (erroneously attributed to Mr. Meyers; Mr. Daignault spoke.)) Count 4 specifies further that

the nucleus to be transferred must be a "cultured diploid bovine fibroblast in the G1 phase of the cell cycle." Stice, in its principal brief, has not directed our attention to any testimony or other evidence indicating that one skilled in the art would have recognized that Stice's sentence teaches or discloses the limitation in count 4 that the transferred nucleus be in the G1 phase of the cell cycle. Similarly, the further limitations that a nucleus be implanted into an unactivated enucleated metaphase II-arrested oocyte, and that the reconstructed embryo be maintained "without activation for a sufficient time to allow the reconstructed embryo to become capable of developing to term," are not apparent from the Stice sentence. Stice has not presented any testimony or other evidence to bridge the gap between the sentence and the subject matter of count 4.

Although Stice relies on Dr. Stice's notebook entry of 27 June 1995, as evidence of diligence, we may consider whether this entry is evidence of conception of an embodiment within the scope of any of the counts. Dr. Stice wrote, "Tried to use the electroporation to introduce β-geo into fibroblast cells bovine (Jose's). The idea is to use these transgenic cells in NT to produce fetuses and offspring? machine?" (Paper 92 at 10.) We have no difficulty accepting that "Jose" refers to co-inventor Cibelli, or that "NT" is an abbreviation for "nuclear transfer."

However, although this passage at least discloses that the nucleus to be transferred is bovine, the other limitations, particularly the G1-phase of the transferred nucleus, are not plainly evident from the text.

Stice, in its principal brief, makes no effort to show that all the limitations required by the count are present in either sentence recorded by Dr. Stice. Nor did Stice, in its principal brief, attempt to show that one skilled in the art would have recognized his statement as a clear idea of an embodiment within the scope of count 4. The significance of data and other documentary exhibits must be explained. See, e.g., 37 CFR § 1.671(f) (2003) ("The significance of documentary and other exhibits identified by a witness in an affidavit or during oral deposition shall be discussed with particularity by a witness"); 37 CFR § 1.608(b) (2003) (similar requirement for discussion of the significance of documents); Standing Order §§ 42, 43 (Paper 2) requiring underlying facts be disclosed that form the basis of expert opinion, and explanations of scientific tests and data). Stice's statement that "[t]he conception corresponds to the subject matter of the Counts" is unsupported by any explanation. When questioned on this point at oral argument, Stice urged that the G1-phase limitation was met inherently by a nucleus taken from a culture of propagating cells. (Paper 120 at 11.) The

board considered and rejected this same general argument from Stice regarding whether the transfer of the nucleus of a "proliferating cell" was inherently met if the nucleus was selected from a proliferating cell culture. (Paper 80 at 37-40, discussion Campbell preliminary motion 3.) As Stice has not come forward with any new evidence or argument, we reject its contention that the missing G1 limitation is inherent.

Moreover, Stice has failed to meet the requirement that inventor testimony regarding conception be corroborated. Kane stated that "I do hereby affirm the research that is reported on those pages [SX 2055 and SX 2056] was performed by the investigators who produced the notebooks. I was given these books to sign in 1997 as signed, even though the work was done earlier." (SX 2052 at 1, ¶2.) This statement is insufficient to establish more than that those pages existed on the date Kane signed them. Kane's statement that "the research . . . was performed" begs the questions of exactly what the laboratory notebook entries indicate Dr. Stice conceived, and how that conception, whatever it was, relates to the limitations of the present counts in this interference. Dr. Cibelli's testimony and laboratory notebooks cannot provide corroboration, as Dr. Cibelli is a co-inventor. Unlike the case of *Jolley*, in which inventor McGraw established by "sufficient circumstantial evidence of an

independent nature," 308 F.3d at 1325, 64 USPQ2d at 1907, Stice has presented no probative evidence corroborating either the substance or the date of Dr. Stice's alleged conception.

Accordingly, we hold that Stice has failed to prove conception of an embodiment within the scope of count 4, prior to Campbell's constructive reduction to practice.

Stice has presented no arguments directed to its prior conception of the subject matter of counts 5 and 6, which relate to ovine (sheep) and porcine (pig) embodiments, respectively. All the evidence put forward by Stice that is arguably prior to Campbell's benefit date of 31 August 1995 relates to inventions involving bovines (cattle). Accordingly, we hold that Stice has failed to demonstrate conception of an embodiment of counts 5 or 6 prior to Campbell's constructive reduction to practice.

Actual reduction to practice

Stice's evidence in support of an actual reduction to practice of an embodiment within the scope of count 4 are similarly deficient. Stice made no attempt, in its principal brief, to explain, with the assistance of relevant evidence, including expert testimony, how the activities reported in Cibelli's research notebook on 30 August 1996, amount to a reduction to practice of an embodiment within the scope of

count 4. There is no explanation, by one skilled in the art, of the significance of the entries in Dr. Cibelli's notebooks relating to actual reduction to practice. Even counsel for Stice appear to have been confused about when critical events occurred. Review of the notebook page for "8/30/96" shows no reference to any "pregnancies from 7/30/96," as alleged by Stice. (Paper 115 at 20.) In response to Campbell's Opposition (Paper 104 at 30-31), Stice admitted, "Dr. Cibelli did not always record everything in his notebook, as evidenced by the lack of an entry for July 30, 1996, despite a reference to activities on that date in the August 30, 1996 entry." (Paper 106 at 20.) In Stice's demonstrative exhibit presented at oral argument, however, the summary for August 30, 1996, refers to "the pregnancies of July 25, 1996." (Paper 122 at 4.) When questioned about the discrepancy between Stice's principal brief and its demonstrative exhibit, counsel for Stice stated that the reference to July 25, 1996 in its brief was a typographical error. (Paper 120 at 16.) At another point, counsel for Stice also stated, "I have seen pages where there are three separate experiments, one related to the count and one related probably to a different project." (Paper 120 at 24.)

These statements by counsel emphasize the necessity of testimony by a witness intimately familiar with laboratory

notebooks. Such records are highly technical, and in practice are often rather abbreviated and idiosyncratic documents. The significance of a given entry or series of entries is often not apparent to an outsider, expert or not, although it may become so if explained. Without such testimony – and commentary, if available, from an opposing expert (or perhaps better, an independent expert) – a lay panel cannot reasonably be assured of coming to any reliable conclusions from its own study of the notebooks. In the absence of testimony explaining and evaluating the experimental procedures, tests, and the conclusions that may be drawn from them, we decline to accord any weight to the unexplained raw data of Cibelli's notebooks.

Moreover, there is no independent evidence in the record corroborating Cibelli's experiments or the results. It is well-settled that an inventor seeking to prove an actual reduction to practice "must provide corroborating evidence in addition to his own statements and documents. Such evidence may consist of testimony of a witness, other than an inventor, to the actual reduction to practice or it may consist of evidence of surrounding facts and circumstances independent of information received from the inventor. The purpose of the rule requiring corroboration is to prevent fraud." *Hahn v. Wong*, 892 F.2d 1028, 1033, 13 USPQ2d 1313, 1317 (Fed. Cir. 1989) (internal quotes and

citations omitted). The general testimony of Blackwell and Kane that the inventors were conducting research in nuclear-transfer techniques and animal cloning does not provide surrounding facts and circumstances sufficient to corroborate an actual reduction to practice of an embodiment within the scope of count 4.

Diligence

Stice's case for diligence is similarly flawed. Its summary of activities is mere attorney argument, unsupported by testimony regarding the underlying work reported in Cibelli's laboratory notebooks. Cibelli's broad description of the research program (SX 2051 at 3-4, ¶¶ 6-7) lacks particularity, and does not suffice to explain his notebook entries. Even regarding the summary, there is no explanation of how the activities relate to the limitations of count 4. In the absence of testimony explaining the relation of the activities reported in Cibelli's notebooks to the subject matter of the counts, and in the absence of testimony explaining the gaps in the record, we are unable to assess the significance of Cibelli's notebooks as they relate to diligent efforts to reduce an embodiment of the invention to practice, and we decline to accord them any weight.

Conclusions

As we have stated repeatedly in other cases, we shall not act as an advocate for either of the parties. When arguing a case concerning a rapidly developing, complicated, highly technical art, it is particularly important to explain how the evidence of record relates to the critical legal issue – here, the counts. The opposing party may then admit or deny the validity of the evidence and its relevance to the issues, providing its own evidence, including expert testimony, if appropriate. Following a reply, the tribunal is then in some reasonable position to weigh the merits of the arguments and to determine whether the moving party has carried its burden. Although Stice's Reply Brief, Paper 106, offers considerably more detailed argument than in its Principal Brief, to the extent it attempts to establish a prima facie case of priority, or any of the underpinnings, it is untimely, and we shall not consider them. No good cause has been shown to present new arguments. It is fundamentally unfair to sit back and wait for an opposition, and then attempt to put together a prima facie case in reply, when the opposing party has no opportunity to contest the belated and newly presented arguments.

ORDER

In view of the foregoing considerations, it is:

ORDERED that Stice has failed to establish, by a preponderance of the evidence, that it conceived an embodiment within the scope of any of counts 4-6, which are all the counts of this interference, before Campbell's constructive reduction to practice;

FURTHER ORDERED that Stice has failed to establish, by a preponderance of the evidence, that it reduced to practice an embodiment within the scope of any of counts 4-6;

FURTHER ORDERED that Stice has failed to establish, by a preponderance of the evidence, that it was diligent in its attempts to reduce to practice an embodiment within the scope of any of counts 4-6.

FURTHER ORDERED that Judgment is entered in Paper 124 which accompanies this decision.

FURTHER ORDERED that this paper be given an appropriate number and placed in the patent file of U.S. Patent 5,945,577 and in the application file of 09/650,194.

FURTHER ORDERED that if there is a settlement, the attentions of the parties are directed to 35 U.S.C. § 135(c) and 37 CFR § 41.205.

FRED E. McKELVEY
Senior Administrative Patent Judge

SALLY GARDNER LANE
Administrative Patent Judge

MARK NAGUMO
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

TRIAL SECTION MERITS PANEL

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20 December 2004

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The opinion in support of the decision being entered today is not binding precedent of the Board.

Paper 124

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Filed
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES
(Administrative Patent Judge Nagumo)

STEVEN L. **STICE**,
JOSE CIBELLI, JAMES ROBL, PAUL GOLUEKE,
F. ABEL PONCE de LEON,
and D. JOSEPH JERRY,

Junior Party,
(Patent 5,945,577)

v.

KEITH HENRY STOCKMAN **CAMPBELL**
and IAN WILMUT,

Senior Party,
(Application 09/650,194).

Patent Interference No. **104,746**

Before: McKELVEY, Senior Administrative Patent Judge, LANE, and NAGUMO, Administrative Patent Judges.

NAGUMO, Administrative Patent Judge.

FINAL JUDGMENT – PRIORITY – Bd. R. 127

In view of the discussion Decision on Priority, Paper 123, it is:

ORDERED that adverse judgment as to priority with respect to counts 4, 5, and 6 is entered against Stice;

FURTHER ORDERED that Steven L. Stice, Jose Cibelli, James Robl, Paul Golueke, F. Abel Ponce de Leon, and D. Joseph Jerry are not entitled to a patent containing claims 1-24 of U.S. Patent 5,945,577;

FURTHER ORDERED that this paper be given an appropriate number and placed in the patent file of U.S. Patent 5,945,577 and in the application file of 09/650,194.

FURTHER ORDERED that if there is a settlement, the attentions of the parties are directed to 35 U.S.C. § 135(c) and 37 CFR § 41.205.

M.cK

FRED E. McKELVEY
Senior Administrative Patent Judge

SALLY GARDNER LANE
Administrative Patent Judge

MARK NAGUMO
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

TRIAL SECTION MERITS PANEL

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Paper 80

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Filed
15 March 2004

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES
(Administrative Patent Judge Sally Gardner Lane)

STEVEN L. **STICE**, JOSE CIBELLI, JAMES ROBL,
PAUL GOLUEKE, F. ABEL PONCE de LEON
and D. JOSEPH JERRY,

Junior Party,
(Patent 5,945,577),

v.

KEITH HENRY STOCKMAN **CAMPBELL**
and IAN WILMUT,

Senior Party,
(Application 09/650,194).

Patent Interference No. **104,746**

Before: SCHAFER, TORCZON, and LANE, Administrative Patent Judges.

LANE, Administrative Patent Judge.

DECISION ON PRELIMINARY MOTIONS

I. Introduction

The interference was declared on 30 January 2002 between junior party Steven L. Stice, Jose Cibelli, James Robl, Paul Golueke, F. Abel Ponce de Leon and D. Joseph Jerry ("Stice") and senior party Keith Henry Stockman Campbell and Ian Wilmut ("Campbell").

Brief summary of the involved technology

Both parties' claims are directed to methods of cloning using a procedure known as nuclear transfer. Both parties have claims directed to cloning a "non-human mammal" and claims that are limited to cloning an ungulate animal (e.g., cow, sheep, and pig).

Nuclear transfer involves, *inter alia*, transferring a donor cell or the nucleus of a donor cell into an enucleated oocyte to form a reconstructed embryo or nuclear transfer unit.[1] The Campbell claims require that the donor cell be a cultured diploid differentiated cell, such as a fibroblast, in the G1 phase of the cell cycle. The Campbell claims also require that, after nuclear transfer, the reconstructed embryo be maintained "without activation for a sufficient time to allow the reconstructed embryo to become capable of developing to term".

The Stice claims require that the donor cell be "a proliferating somatic cell that has been expanded in culture" but do not specify that a donor cell in the G1 phase of the cell cycle is required. Some of the Stice claims recite a separate step of "activating" the reconstructed embryo but none of the claims recites a step of maintaining the reconstructed embryo "without

---

[1] Campbell uses the term reconstructed embryo while Stice uses the term nuclear transfer unit. In this decision, we will use the term reconstructed embryo to refer to what results when a donor cell or donor cell nucleus is transferred into an enucleated oocyte.

activation for a sufficient time to allow the reconstructed embryo to become capable of developing to term".

The level of skill in the art may be inferred from the references of record and the background of the witnesses, *In re GPAC*, 57 F.3d 1573, 1579, 35 USPQ2d 1116, 1121 (Fed. Cir. 1995); *Enzo Biochem., Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1373, 52 USPQ2d 1129, 1137 (Fed. Cir. 1999) .

Summary of the decision

Stice moves for judgment that the Campbell claims are unpatentable under the written description requirement of 35 USC §112, ¶1, and, in a separate motion, under 35 USC §112, ¶2, on the basis that the Campbell invention as described in the specification requires a step that is not found in the claims, i.e., a step of maintaining correct ploidy of the reconstructed embryo.

Stice moves for judgment that there is no interference-in-fact between its claims and Campbell's claims on the basis that the Stice claims and the Campbell claims use patentably distinct donor cells and patentably distinct method steps.

We DENY each Stice preliminary motion.

Campbell moves to redefine the interference by substituting a count that is, in essence, a combination of each of the present counts. We DENY the Campbell preliminary motion.

Campbell moves for judgment that the Stice claims are unpatentable under the written description requirement of 35 USC §112, ¶1, on the basis that the Stice specification does not provide support for a donor cell that is "proliferating". We GRANT the Campbell preliminary motion.

Campbell moves to be accorded priority benefit of an earlier filed application as to each of the present counts, and, contingently, for priority benefit of the application as to the substitute count. We GRANT Campbell's preliminary motion to be accorded priority benefit as to each of the present counts.

We DISMISS as moot the remaining Campbell preliminary motions.

II. Findings of fact

The record supports the following findings of fact as well as any other findings of fact set forth in any other portion of the decision by at least a preponderance of the evidence.

The interference

1. Stice is involved in the interference on the basis of its 5,945,577 ("'577") patent, issued on 31 August 1999 and based on application 08/781,752, filed 10 January 1997.
2. In this decision, when we refer to the Stice specification we are referring to the '577 specification.
3. According to Stice, its real party in interest is "the University of Massachusetts, who has exclusively licensed their interest to Advanced Cell Technology Corporation" (Paper 9).
4. Campbell is involved in the interference on the basis of its 09/650,194 ("'194") application, filed 29 August 2000.
5. In this decision, when we refer to the Campbell specification we are referring to the '194 specification.

6. According to Campbell, its real party in interest is (1) Assignee: Roslin Institute (Edinburgh) of Midlothian, England; (2) licensees: Geron Corporation, of Menlo Park, CA and PPL Therapeutics Ltd of Midlothian, England (Paper 79).

The counts

7. The interference was declared with three counts: Count 1, Count 2, and Count 3.

8. **Count 1** is as follows (Paper 1 at 5):

> A method according to any of claims 1, 2, 3, 4, 5, or 6 of Stice patent 5,945,577, where the "non-human mammal" is a cow or a bovine and where the "non-human mammalian fetus" is a cow fetus or a bovine fetus,
>
> or
>
> a method according to any of claims 19 or 23 of Campbell application 08/803,165.[2]

9. **Count 2** is as follows (Paper 1 at 6):

> A method according to any of claims 1, 2, 3, 4, 5, or 6 of Stice patent 5,945,577, where the "non-human mammal" is a sheep or an ovine and where the "non-human mammalian fetus" is a sheep fetus or an ovine fetus,
>
> or
>
> a method according to any of claims 27 or 31 of Campbell application 08/803,165.

10. **Count 3** is as follows (Paper 1 at 7):

> A method according to any of claims 1, 2, 3, 4, 5, or 6 of Stice patent 5,945,577, where the "non-human mammal" is a pig or a porcine and where the "non-human mammalian fetus" is a pig fetus or a porcine fetus,
>
> or

---

[2] Each of Counts 1 through 3 incorrectly refers to the parent of the involved Campbell application. The Campbell application referred to in Counts 1 through 3 should be the involved Campbell application, i.e., 09/650,194.

a method according to any of claims 35 or 39 or 43 or 47 of Campbell application 08/803,165, where the "non-human mammal" is a pig or a porcine and where the "non-human mammalian fetus" is a pig fetus or a porcine fetus.

11. Stice claim 1 is as follows:

> An improved method of cloning a non-human mammal by nuclear transfer comprising the introduction of a non-human mammalian donor cell or a non-human mammalian donor cell nucleus into a non-human mammalian enucleated oocyte of the same species as the donor cell or donor cell nucleus to form a nuclear transfer (NT) unit, implantation of the NT unit into the uterus of a surrogate mother of said species, and permitting the NT unit to develop into the cloned mammal, wherein the improvement comprises using as the donor cell or donor cell nucleus a proliferating somatic cell that has been expanded in culture, or a nucleus isolated from said somatic cell.

12. Stice claims 2 through 6 are similar to Stice claim 1. The follow differences are noted:

(a) claim 2 requires that "the donor cell or donor cell nucleus has been genetically transformed to comprise at least one addition, substitution or deletion of a nucleic acid sequence."

(b) claim 3 requires the steps of activating the reconstructed embryo and culturing the activated reconstructed embryo "until greater than the 2-cell developmental phase" before transfer to a non-human host mammal.

(c) claim 4 is directed to "an improved method of cloning a non-human mammalian fetus".

(d) claim 5 is directed to "an improved method of cloning a non-human mammalian fetus" and requires that "the donor cell or donor cell nucleus has been genetically transformed to comprises [sic-comprise] at least one addition, substitution or deletion of a nucleic acid sequence."

(e) claim 6 is directed to a method of cloning "a non-human mammalian fetus" and requires the steps of activating the

reconstructed embryo and culturing the activated reconstructed embryo "until greater than the 2-cell developmental phase" before transfer to a non-human host mammal.

13. Claim 19 of Campbell is as follows:

A method of cloning a cow by nuclear transfer comprising:

(i) inserting a nucleus of a cultured diploid bovine fibroblast in the G1 phase of the cell cycle into an unactivated, enucleated metaphase II-arrested bovine oocyte to reconstruct an embryo;

(ii) maintaining the reconstructed embryo without activation for a sufficient time to allow the reconstructed embryo to become capable of developing to term;

(iii) activating the resultant reconstructed embryo;

(iv) culturing said activated, reconstructed embryo to blastocyst; and

(v) transferring said cultured, reconstructed embryo to a host cow such that the reconstructed embryo develops to term.

14. The other Campbell claims referred to in the counts are also directed to a method of cloning by nuclear transfer comprising the same steps as Campbell claim 19. The following differences are noted:

(a) Campbell claim 23 is directed to a method of cloning a bovine fetus.

(b) Campbell claim 27 is directed to a method of cloning a sheep.

(c) Campbell claim 31 is directed to a method of cloning an ovine fetus.

(d) Campbell claim 35 is directed to a method of cloning a non-human mammal.

(e) Campbell claim 39 is directed to a method of cloning a non-human mammalian fetus.

(f) Campbell claim 43 is directed to a method of cloning a non-human mammal and requires that the donor cell be a differentiated cell.

(g) Campbell claim 47 is directed to a method of cloning a non-human mammalian fetus and requires that the donor cell be a differentiated cell.

Claim correspondence

15. The following claims are designated as corresponding to **Count 1** (Paper 1 at 5):

Stice: 1-24

Campbell: 19-26 and 35-50

16. The following claims are designated as corresponding to **Count 2** (Paper 1 at 6):

Stice: 1-22

Campbell: 27-50

17. The following claims are designated as corresponding to **Count 3** (Paper 1 at 7):

Stice: 1-22

Campbell: 35-51[3].

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[3] Campbell was authorized to file an amendment adding claim 51 to its involved application (Paper 32 at 2). Campbell claim 51 is directed to a method of cloning a pig using the nuclear transfer method and thus corresponds to Count 3.

Benefit

18. Stice was not accorded priority benefit of the filing date of any prior application (Paper 1 at 3).

19. Campbell was accorded priority benefit of the following two applications for all three counts of the interference (Paper 1 at 4):

> US application 08/803,165, filed 19 February 1997 and issued as patent 6,252,133 on 26 June 2001, and
>
> PCT application PCT/GB96/02098, filed 30 August 1996.

Stice motions

20. Stice filed the following motions:

(a) Stice preliminary motion 1 under 37 CFR § 1.633(b) for a judgment that there is no interference-in-fact (Paper 22).

(b) Stice preliminary motion 2 under 35 CFR § 1.633(a) seeking judgment that the involved Campbell claims are unpatentable under 35 USC § 112, ¶ 1 (Paper 23).

(c) Stice preliminary motion 3 seeking judgment that the involved Campbell claims are unpatentable under 35 USC § 112, ¶ 2 (Paper 24).

Campbell motions

21. Campbell filed the following motions:

(a) Campbell preliminary motion 1 under 37 CFR § 1.633(c)(1) seeking to substitute proposed count 4 for Counts 1 through 3 (Paper 28).

(b) Campbell preliminary motion 2 under 37 CFR § 1.633(f) seeking to be accorded priority benefit of an earlier filed application (Paper 29).

(c) Campbell preliminary motion 3 under 37 CFR § 1.633(a) seeking judgment that the involved Stice claims are unpatentable for failing to comply with the written description requirement of 35 USC § 112, ¶ 1 (Paper 30).

(d) Campbell preliminary motion 4 under 37 CFR § 1.633(a) seeking judgment that the involved Stice claims are unpatentable for failing to comply with the enablement requirement of 35 USC § 112, ¶ 1 (Paper 31).

(e) Campbell responsive preliminary motion 5 under 37 CFR § 1.633(c)(2) seeking to add claims to the '194 application (Paper 40).

(f) Campbell responsive preliminary motion 6 under 37 CFR § 1.633(c)(1) seeking to substitute proposed count 5 for Counts 1 through 3 (Paper 41).

(g) Campbell responsive preliminary motion 7 under 37 CFR § 1.633(f) seeking to be accorded priority benefit of the filing date of earlier filed applications as to proposed count 5 (Paper 42).

Stice preliminary motions 2 and 3

22. According to Stice preliminary motion 2, the Campbell disclosure does not provide § 112, ¶ 1, written description for the subject matter claimed by Campbell.

23. According to Stice preliminary motion 3, the Campbell claims are indefinite under § 112, ¶ 2, because Campbell's claims do not define what Campbell regards as the invention (Paper 24 at 2).

24. Stice makes many of the same arguments in its preliminary motion 3 that it makes in its preliminary motion 2.

25. The gist of Stice's arguments in both its preliminary motions 2 and 3 is that Campbell's specification describes a nuclear transfer procedure that requires a step of maintaining correct ploidy during activation of the reconstructed embryo through the use of a microtubule inhibitor or stabilizer (Paper 23 at 18-19 and Paper 24 at 18-19).

26. In support of its preliminary motions 2 and 3, Stice relies upon the testimony of Dr. Jorge A. Piedrahita (Exh. 2002).

27. According to Dr. Piedrahita a step of maintaining correct ploidy is an integral part of Campbell's invention and is achieved by using a G0 or G1 donor cell nucleus and incubating the activated oocyte in the presence of a microtubule inhibitor such as nocodazole. (Exh. 2002 at ¶¶ 10-12).

28. According to Dr. Piedrahita, Table 2 of the Campbell application indicates that a microtubule inhibitor is used to maintain correct ploidy. (Exh. 2002 at ¶ 12).

29. According to the Campbell specification, "Table 2 shows pronuclear formation in enucleated oocytes fused to primary bovine fibroblasts" and shows a comparison of pronuclei formation in oocytes that were treated with nocodazole (Group A) and those that were not treated with nocodazole (Group B)." (Exh. 2001 at 24).

30. Table 2 is reproduced below (Exh. 2001 at 24):

	TOTAL	1 PN[4]	2 PN	3 PN	4 PN	>4 PN
GROUP A	52	100	0	0	0	0
GROUP B	33	45.2	25.8	16.1	3.2	9.7

31. According to the Campbell specification, "[i]n the practice of the invention, correct ploidy must be maintained during activation" and "[i]t is desirable to inhibit or stabilise microtubule polymerization in order to prevent the production of multiple pronuclei, thereby to maintain correct ploidy." (Exh. 2001 at 14).

32. According to Table 2, the formation of multi pronuclei was avoided 100% of the time in oocytes treated with nocodazole and 45.2% of the time in untreated oocytes. (Exh. 2001 at 24).

33. Stice argues that the original claims in Campbell's involved application included the limitation of "maintaining correct ploidy" of the reconstructed embryo.

34. Stice argues that Campbell amended claims in another of its applications[5] to include the limitation of "maintaining correct ploidy" in response to the examiner's rejections under 35 USC § 112, ¶1 and ¶2.

---

4 Pronuclei.

5 Application 08/803,165 which issued as patent 6,252,133 on 26 June 2001 (Paper 22 at 10).

35. The Campbell specification states the following (Exh. 2001 at 2-3):

> ...we have shown that maintenance of correct ploidy during the first cell cycle of the reconstructed embryo is of major importance.

and (Exh. 2001 at 3-4):

> In reconstructed embryos correct ploidy can be maintained in one of two ways; firstly by transferring nuclei at a defined cell cycle phase, e.g. diploid nuclei of cells in G1, into metaphase II oocytes at the time of activation...

and (Exh. 2001 at 7):

> Donors which are diploid at the time of transfer are necessary in order to maintain the correct ploidy of the reconstituted embryo; therefore donors may be either in the G1 phase or preferably,...in the G0 phase of the cell cycle.

and (Exh. 2001 at 19-20):

> This protocol has a number of advantages over previously published methods of nuclear transfer:
> 1).....
> 2) Correct ploidy of the reconstituted embryo is maintained when G0/G1 nuclei are transferred....

Stice preliminary motion 1

36. According to Stice, its claims and Campbell's claims do not interfere-in-fact (Paper 22 at 1).

37. Stice argues that:

(a) Campbell's claims, when properly construed, require the maintenance of correct ploidy of the reconstructed embryo while Stice's claims do not require a step of maintaining correct ploidy (Paper 22 at 14-17),

(b) Campbell's claims require a donor cell that is in the G1 phase of the cell cycle while Stice's claims require a donor cell that is proliferating (Paper 22 at 18-20),

(c) Campbell's claims require a step of maintaining the reconstructed embryo without activation for a sufficient time to allow the reconstructed embryo to become capable of developing to term while Stice's claims do not require that activation be prevented after nuclear transfer (Paper 22 at 20-22).

Dr. Piedrahita's testimony

38. Stice relies upon the declaration testimony of Dr. Piedrahita to support its preliminary motion 1. (Exh. 2002).

39. Dr. Piedrahita testified that the claimed invention of Campbell would not be obvious over the claimed invention of Stice and *vice versa* (Exh. 2002 at ¶¶ 29 and 30).

The maintenance of ploidy limitation:

40. Dr. Piedrahita testified that the invention of Campbell would not suggest a nuclear transfer cloning method that would function effectively in the absence of a step of maintaining correct ploidy. (Exh. 2002 at ¶ 30).

The donor cell limitation:

41. Dr. Piedrahita testified that a proliferating cell exists in either the G1, S, G2 or M phase of the cell cycle. (Exh. 2002 at ¶ 21).

42. The parties agree that the majority of cultured proliferating mammalian somatic cells are in the G1 phase of the cell cycle. (Paper 45 at 10 and Paper 57 at 4).

43. However, according to Dr. Piedrahita, G1 cells are not necessarily proliferating cells since, for example, cells can become arrested in the G1 phase of the cell cycle in response to DNA damage or in response to activation of tumor suppressor genes or exposure to antiproliferative agents. (Exh. 2002 at ¶ 32).

44. Dr. Piedrahita testified that (Exh. 2002 at ¶ 16):

> [M]ethods for distinguishing G1 cells from cells in other phases of the cell cycle were not known to those skilled in the art at the time. The only procedure for selecting a G1 cell was to synchronize the cells so that all of the cells in culture were in the G1 phase.

The "without activation" limitation:

45. Dr. Piedrahita testified that the Campbell claimed invention would not have been obvious over the Stice claimed invention, and *vice versa*, since "[n]o steps are contained in the Stice claims which would prevent activation simultaneously with or immediately following nuclear transfer". (Exh. 2002 at ¶¶ 34 and 35).

46. Dr. Piedrahita testified that "the only teaching Campbell provides for delaying activation during the 'maintaining' step (ii) is to incubate the reconstructed embryo in a calcium-free medium" while the Stice specification teaches using a medium that contains calcium ions. (Exh. 2002 at ¶¶ 19 and 25).

Dr. Wells' testimony

The donor cell limitation:

47. Campbell witness Dr. David Wells testified as follows (Exh. 1037 at ¶ 11):

Based on my experience in isolating cells in various stages in the cell cycle, in the absence of any designation or notation that a G1 cell is not proliferating, I would assume that a cell designated simply as a G1 cell was proliferating.

48. Dr. Wells testified that if a cell in G1 was not proliferating, e.g., the cell was arrested in G1, then an indication to that effect is usually given. (Exh. 1037 at ¶ 10).

49. Dr. Wells testified that an article by Kauffman in 1990[6] describes counterflow centrifugal elutriation as a technique that could be used to isolated cultured cells in a specific phase of the cell cycle. (Exh. 1037 at ¶ 29).

50. According to Campbell, the technique described in the Kauffman article allows for isolation of G1 cells without the need for synchronization. (Paper 45 at 2-3).

The Campbell specification

51. The Campbell specification states that (Exh. 2001 at 12):

> In a preferred embodiment of the invention, fusion of the oocyte karyoplast couplet is accomplished in the absence of activation by electropulsing in 0.3 mannitol solution or 0.27 sucrose solution; alternatively the nucleus may be introduced by injection in a calcium free medium. The age of the oocyte at the time of fusion/injection and the absence of calcium ions from the fusion/injection medium prevent activation of the recipient oocyte.

52. According to Campbell's specification the reconstructed embryo is "returned to the maturation medium [and] is maintained without being activated" (Exh. 2001 at 12).

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[6] Kauffman et al., *Analytical Biochemistry*, 191:41-46 (1990).

53. Dr. Wells testified that he is familiar with the maturation medium described in the Campbell specification, i.e. "TC medium 199 with Earles salts (Gibo)", (Exh. 2001 at 22) and that the medium contains calcium. (Exh. 1037 at ¶¶ 72-74).

Campbell preliminary motion 1

54. Campbell preliminary motion 1 under 37 CFR § 1.633(c)(1), seeks to redefine the interfering subject matter by substituting proposed Count 4 for Counts 1 through 3.

55. Proposed count 4 is essentially a combination of Counts 1 through 3.

56. Proposed count 4 reads as follows (Paper 28 at 2-3):

> A method according to any of claims 1,2,3,4,5, or 6 of Stice patent 5,945,577, where the 'non-human mammal' is a bovine, ovine, or porcine and where the 'non-human mammalian fetus' is a bovine, ovine or porcine fetus, or a method according to any of claims 19, 23, 27, 31, 35, 39, 43, 47, or 51 [footnote omitted] of Campbell application 09/650,194 [footnote omitted], where the 'non-human mammal' is a bovine, ovine, or porcine and where the 'non-human mammalian fetus' is a bovine, ovine, or porcine fetus.

57. According to Campbell, it is appropriate to combine Counts 1 through 3 into one count since Counts 1 through 3 are not directed to inventions that are separately patentable from one another.

58. In particular, Campbell argues that neither its specification and claims, the Stice specification and claims, nor the examiner treated the subject matter of Counts 1 through 3 as being separately patentable subject matter.

Campbell preliminary motion 3

59. Each of Stice's claims is directed to a nuclear transfer method using a donor cell that is "a proliferating cell that has been expanded in culture".

60. In its preliminary motion 3, Campbell argues that the Stice claims are unpatentable for failing to provide written description in the specification for the use of a donor cell that is "proliferating" (Paper 30 at 1).

61. Stice's specification does not use the term "proliferating" to describe the donor cell (Paper 51 at 3).

62. Stice states that "the present invention is novel because differentiated cell types are used" (Exh. 2004 at 8:31-34) and that "it was unexpected that cloned embryos with differentiated donor nuclei could develop to advanced embryonic and fetal stages." (Exh. 2004 at 6:22-24).

63. The Stice specification states that (Exh. 2004 at 8:4-9):

> Differentiated mammalian cells are those cells which are past the early embryonic stage. More particularly, the differentiated cells are those from at least past the embryonic disc stage (day 10 of bovine embryogenesis). The differentiated cells may be derived from ectoderm, mesoderm or endoderm.

64. Differentiated cells may be described as proliferating or non-proliferating (Paper 30 at 6 and Paper 51 at 2).

65. Cells that are "proliferating" are in the G1, S, G2, or M phase of the cell cycle (Paper 51 at 4 and Paper 61 at 1).

66. The parties agree that cells in the G0 phase of the cell cycle are "quiescent" and are not "proliferating" (Paper 51 at 4 and Paper 61 at 1).

67. Stice's specification states that (Exh. 2004 at 8:24-34) :

> Fibroblast cells are an ideal [donor] cell type...these cells can be easily propagated in vitro with a rapid doubling time and can be clonally propagated for use in gene targeting procedures. Again the present invention is novel because differentiated cells are used. The present invention is advantageous because the cells can be easily propagated, genetically modified and selected in vitro.

68. Stice argues that its specification describes proliferating donor cells in that it describes "propagating" fibroblast donor cells and shows, at its example 1, fibroblasts, being isolated, grown in culture, and then used in the nuclear transfer procedure as donor cells (Paper 51 at 5-8).

69. Fibroblasts are differentiated cells and can be either proliferating or non-proliferating (Paper 30 at 6 and Paper 51 at 3).

70. Fibroblasts can be in any phase of the cell cycle, including the G0 phase (Paper 30 at 6 and Paper 51 at 3).

Dr. Piedrahita's testimony

71. In opposing Campbell's preliminary motion 2, Stice relies upon the declaration testimony of Dr. Piedrahita. (Exh. 2025).

72. Dr. Piedrahita testified as follows:

(a) If cells in culture are propagated, those cells are proliferating cells. (Exh. 2025 at ¶ 5).

(b) One line of cells, i.e., the CL-1 line, which was derived from a propagating colony of fibroblast cells, was used as the source of

donor cells for the nuclear transfer procedure described at example 1 of the '577 specification. (Exh. 2025 at ¶ 7).

(c) The culture conditions described in example 1 are typical for propagating a proliferating cell culture. In such a cell culture most of the fibroblasts are in the G1 phase of the cell cycle (Exh. 2025 at ¶¶ 10 and 11).

73. Dr. Piedrahita relied upon an article by Boquest[7] in support of his testimony that most fibroblasts in the culture described in Stice example 1 would be in the G1 phase of the cell cycle.

74. The Boquest article was published in 1999 and thus is not prior art to either Stice or Campbell.

75. The Boquest article indicates that most, but not all, of the cultured fibroblasts studied were in the G1 phase of the cell cycle.

76. For example, at Table 1 of the article it is reported that 2.8 ± 1.2 % of the fibroblasts in the described propagating[8] culture were in the G0 phase of the cell cycle. (Exh. 2027 at 1016).

Dr. Wells' testimony

77. Regarding the proliferation of fibroblasts in culture, Campbell witness Dr. Wells testified that (Exh. 1026 at ¶ 35):

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[7] Boquest et al., *Biology of Reproduction*, **60**:1013-1019 (1999). (Exh. 2027).

[8] Boquest uses the term "cycling" which Stice states is synonymous with "propagating" (Paper 51 at 5 and Exh. 2025 at ¶ 6). Campbell seems to agree (Paper 61 at 1).

Based on my experience using proliferating cultured fibroblasts in various phases of the cell cycle, proliferation is not a process that all fibroblasts in culture inherently undergo at all stages of their lifecycle. Fibroblast cells can be proliferating or non-proliferating. Fibroblast cells can be in the M, G_1, S, G_2 phase of the cell cycle, or in the G_0 state.

Campbell preliminary motion 2

78. Campbell moves to be accorded priority benefit of United Kingdom patent application GB 9517779.6 (Exh. 1003) ("the GB application"), filed 31 August 1995.

79. The disclosure of the GB application is substantially the same as the disclosure of the involved Campbell application.

80. Stice argues that the GB application does not provide written description support for the subject matter of Counts 1 through 3.

81. In its opposition 2, Stice relies upon substantially the same arguments and evidence[9] Stice relied upon to support its preliminary motions 2 and 3.

III. Discussion

A. Stice preliminary motion 2

In its preliminary motion 2, Stice moves for judgment that the Campbell claims are unpatentable for failing to comply with the written description requirement of 35 USC §112, ¶1. According to Stice, the Campbell claims lack written description support because they omit an

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[9] Stice relies upon a second declaration of Dr. Piedrahita (Exh. 2025). Dr. Piedrahita's testimony regarding the GB application is substantially the same as his testimony regarding Campbell's involved application.

"essential step and critical element of the invention, the maintenance of ploidy during the activation step." (Paper 23 at 2). As the moving party, Stice has the burden of proof to show that it is entitled to the relief sought in its motion. 37 CFR § 1.637(a). As Stice has not met its burden, we DENY Stice preliminary motion 2.

In order to meet the written description requirement the specification must clearly convey to those skilled in the art that the applicant invented the claimed subject matter. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1562-63, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). As Stice points out, a claim should be no broader than its supporting disclosure, *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479-80, 45 USPQ2d 1498, 1503 (Fed. Cir. 1998). Thus, a claim directed to an invention that is broader in scope than the invention described in the specification may be unpatentable for failing to comply with the written description requirement of 35 USC § 112, ¶1.

While Campbell's specification recognizes the importance of maintaining correct ploidy within the reconstructed embryo, none of the involved Campbell claims recites a step of maintaining correct ploidy of the reconstructed embryo during activation. Stice argues that Campbell's claims are not adequately described by the Campbell specification since the specification describes the maintenance of ploidy step as critical to the invention. (Paper 23 at 17).

Regarding the maintenance of ploidy, Dr. Piedrahita testified that a step of maintaining correct ploidy is an integral part of Campbell's invention and is achieved by using a G0 or G1

donor cell nucleus and incubating the activated oocyte in the presence of a microtubule inhibitor such as nocodazole. (FF[10] 27).

Regarding the maintenance of correct ploidy, the Campbell specification states the following (FF 35):

> ...we have shown that maintenance of correct ploidy during the first cell cycle of the reconstructed embryo is of major importance.

and:

> In reconstructed embryos correct ploidy can be maintained in one of two ways; firstly by transferring nuclei at a defined cell cycle phase, e.g. diploid nuclei of cells in G1, into metaphase II oocytes at the time of activation...

and:

> Donors which are diploid at the time of transfer are necessary in order to maintain the correct ploidy of the reconstituted embryo; therefore donors may be either in the G1 phase or preferably,...in the G0 phase of the cell cycle.

and:

> This protocol has a number of advantages over previously published methods of nuclear transfer:
> 1).....
> 2) Correct ploidy of the reconstituted embryo is maintained when G0/G1 nuclei are transferred....

We appreciate, based on what is stated in the Campbell specification and our own understanding of the art, that it is crucial to successful cloning that correct ploidy be maintained throughout the process. However, Stice has not directed us to evidence demonstrating that correct ploidy is not maintained as stated and claimed in the Campbell claims, i.e., by

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[10] Finding of fact.

transferring nuclei of cells in the G1 phase of the cell cycle into metaphase II oocytes. Stice has not explained why Campbell would need to include a step of "maintaining correct ploidy" in its claims when correct ploidy is inherently maintained by following steps recited in Campbell's claims.

Stice argues that the Campbell specification teaches that a microtubule inhibitor or stabilizer is necessary to maintaining ploidy (Paper 23 at 18-19). However, neither the Campbell specification nor the evidence pointed out to us by Stice supports this argument.

As noted by Stice, the Campbell specification says that it is "desirable" to inhibit or stabilize microtubule polymerization to maintain correct ploidy. (FF 31). Thus our understanding from reading the Campbell specification is that a microtubule inhibitor or stabilizer, such as nocodazole, would have been advantageous in performing the method claimed by Campbell, but was not required. Stice has not directed us to evidence that contradicts our understanding.

According to Dr. Piedrahita, Table 2 of the Campbell specification indicates that a microtubule inhibitor is used to maintain correct ploidy. (FF 28). Stice argues that results set forth at Table 2 of the Campbell specification indicate that it was necessary to incubate the activated oocyte in the presence of a microtubule inhibitor to maintain correct ploidy. According to Table 2, the formation of multi pronuclei was avoided 100% of the time in oocytes treated with nocodazole and 45.2% of the time in untreated oocytes. (FF 30).

The Table 2 results indicate that the nuclear transfer procedure works better when a microtubule inhibitor is used. However, the results do not show that a microtubule inhibitor is necessary to maintain correct ploidy since correct ploidy was maintained in 45.2% of the

reconstructed embryos without the use of an microtubule inhibitor. The results at Table 2 are consistent with Campbell's specification statement that it is "desirable" to use a microtubule inhibitor. The Table 2 results, particularly when considered in view of the entirety of Campbell's specification, do not indicate that Campbell considered the use of an inhibitor to be a necessary part of its invention.

Stice argues that during *ex parte* prosecution Campbell improperly broadened the scope of the present claims by removing a limitation that was in the allowed claims in Campbell's parent application. According to Stice, the claims in Campbell's parent application were amended to include a limitation of "maintaining correct ploidy" or a limitation of using "a microtubule inhibitor or stabilizer" in response to the examiner's rejections of the claims under 35 USC § 112, ¶¶ 1 and 2. Stice argues that by amending the claims as Campbell did Campbell "acquiesc[ed] in the Examiner's position that maintaining correct ploidy was a critical element or step of Campbell's invention" (Paper 23 at 22). In support of its position, Stice cites *Biovail Corp. Int'l v. Andrx Phars.*, Inc., 239 F.3d 1297, 1301-1302, 57 USPQ2d 1813, 1816-1817 (Fed. Cir. 2001). The *Biovail* case was an infringement case involving the application of the doctrine of equivalents. Stice has not explained how it is relevant to whether or not Campbell has complied with the written description requirement.

At any rate, Stice has not explained why Campbell's claims are not already directed to a method where correct ploidy is maintained. In particular, Stice has not shown why one reading the Campbell specification would not have understood that correct ploidy is inherently maintained by following steps recited in the Campbell claims, i.e., by using a donor cell that is diploid at the time of nuclear transfer.

Stice has not sufficiently shown why we should enter judgment that Campbell's claims are unpatentable under the written description requirement of 35 USC § 112, ¶1. We DENY Stice preliminary motion 2.

B. Stice preliminary motion 3

In its preliminary motion 3, Stice argues that the Campbell claims are unpatentable under 35 USC § 112, ¶2 for failing to adequately define the invention in that the claims omit a step that Campbell considered to be an essential part of its invention, i.e., the step of "maintaining ploidy during activation" (Paper 24 at 1).

As the moving party, Stice has the burden of proof to show that it is entitled to the relief sought in its motion. 37 CFR § 1.637(a). As Stice has not met its burden, we DENY Stice preliminary motion 3.

Stice's arguments are similar to the arguments Stice made in its preliminary motion 2. The gist of Stice's position is that Campbell's claims do not properly define the invention because the claims omit the step of maintaining ploidy during activation.

For reasons stated above, we are not persuaded that a separate step of maintaining ploidy is required by the Campbell specification. Stice has not shown that one reading the Campbell specification would not have understood that ploidy is inherently maintained by following steps recited in the Campbell claims, i.e., by selecting a donor cell that is in the G1 phase of the cell cycle.

Stice has not shown that the Campbell claims fail to properly define the invention as required by 35 USC § 112, ¶ 2. Stice preliminary motion 3 is DENIED.

C. *Stice preliminary motion 1*

Stice moves for judgment that there is no-interference-in-fact between its claims and Campbell's claims. As the moving party, Stice has the burden of proof to show that it is entitled to the relief sought in its motion. 37 CFR § 1.637(a). As Stice has not met its burden, we DENY Stice preliminary motion 1.

To show that no interference-in-fact exists Stice must prove either that: (1) its claims would not have been anticipated or rendered obvious by Campbell's claims or, (2) Campbell's claims would not have been anticipated or rendered obvious by Stice's claims. *Eli Lilly & Co. v. Bd. Of Regents of the Univ. of Wash.*, 334 F.3d 1264, 1270, 67 USPQ2d 1161, 1165 (Fed. Cir. 2003).

Stice argues that its claims and Campbell's claims do not interfere-in-fact because (1) Campbell's claims require a step of the maintaining ploidy and Stice's claims do not, (2) Campbell's claims use a donor cell that is in the G1 phase of the cell cycle while Stice's claims use a "proliferating" donor cell, and (3) Campbell's claims require a step of maintaining the reconstructed embryo without activation for a sufficient time to allow the reconstructed embryo to become capable of developing to term and Stice's do not (Paper 24 at 14, 18, 20, and 21).

Maintenance of ploidy

According to Stice, Campbell's claims, to be valid, must require a means for maintaining ploidy, i.e., adding a microtubule inhibitor or stabilizer. In particular, Stice argues that if Campbell's claims are not construed to require a means for maintaining ploidy then the claims

are invalid for lack of written description support. Stice argues that its claims do not require a means for maintaining ploidy and thus are patentably distinct from Campbell's claims.

Stice's arguments as to why the Campbell claims should be construed to include a step of maintaining ploidy through the use of a microtubule stabilizer or inhibitor are similar to the arguments Stice made in its preliminary motions 2 and 3. For reasons stated above, the arguments are unpersuasive.

Stice has not shown that the Campbell claims should be construed to require the addition of a microtubule inhibitor or stabilizer. As we stated above, one reading the Campbell specification would have understood that correct ploidy is inherently maintained by following steps recited in the Campbell claims, i.e., by selecting a donor cell in the G1 phase of the cell cycle. Thus, Stice has not shown that its and Campbell's claims are patentably distinct on the basis that the Campbell claims require a means for maintaining ploidy.

The donor cell limitation

Stice argues that its and Campbell's claims are patentably distinct based on the difference in donor cells used in their respective claimed methods. In particular, Stice argues that its claims and Campbell's claims are patentably distinct because the Stice claims require a "proliferating" donor cell while the Campbell claims require a donor cell that is in the G1 phase of the cell cycle.

According to Stice, the G1 cells used in Campbell's claims had to be obtained by synchronization and isolation since this was the only way known to obtain G1 cells at the time of the invention. Stice argues that these synchronized G1 cells are not the same as the proliferating cells required by Stice's claims since the proliferating cells can exist in any of the four phases of the cell cycle.

Stice argues that its claims are not anticipated by Campbell's claims as to the donor cell limitation. However, according to Stice, proliferating cells may be, and most proliferating cells in culture are, in the G1 phase of the cell cycle. (FFs 42 and 65). Thus, it would seem that a cell in the G1 phase of the cell cycle would anticipate a "proliferating" cell limitation.

Stice notes that Campbell's preferred embodiment is to a non-proliferative donor cell, i.e., a G0 cell, indicating that Campbell intended to use non-proliferating cells in its methods. However, Campbell's claims all require a G1 donor cell, not a G0 cell.

Stice argues that G1 cells are not necessarily proliferating cells because the cells may be arrested or synchronized in the G1 phase. According to Stice, certain factors, e.g., DNA damage, or exposure to antiproliferative agents may cause cells to arrest in G1. (FF 43). Stice has not sufficiently explained why we should read Campbell's claims as requiring a donor cell that is arrested in G1. For example, Stice has not pointed out where the Campbell specification teaches that its donor cells were damaged or exposed to antiproliferative agents. In this regard, we credit Dr. Wells testimony that a cell designated as being in the G1 phase of the cell cycle would be presumed to be proliferating in the absence of indication to the contrary. (FF 48).

Moreover, Stice has not sufficiently shown the only way known to isolate G1 cells during the relevant time period was to synchronize them. Dr. Piedrahita testified that G1 cells could only be obtained by synchronization during the relevant time period (FF 44). Dr. Wells testified that there were many ways of isolating G1 cells during the relevant time period. According to Campbell, at least one of the techniques described in the prior art discussed by Dr. Wells in his testimony did not require synchronization. (FF 50). Stice does not dispute

Campbell's argument in its reply. We do not credit Dr. Piedrahita's testimony that G1 cells could only be isolated by synchronization during the relevant time frame.

According to Stice, assuming the claimed invention of Stice to be prior art to Campbell, "the claimed invention of Stice would not anticipate the claimed invention of Campbell, because the invention of Stice...uses as the donor cell a proliferating (and thus unsynchronized) cell, whereas the claimed invention of Campbell...uses as the donor cell an isolated diploid cell in the G1 phase" (Paper 22 at 19).

The disclosure of a small genus may anticipate a species even if that species is not named. *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1380, 58 USPQ2d 1508, 1517 (Fed. Cir. 2001). Nonetheless, even if we accept Stice's argument that its donor cell limitation does not anticipate Campbell's, Stice has not shown why the selection of a G1 donor cell would not have been obvious in view of Stice's claims. According to Stice, assuming the claimed invention of Stice to be prior art to Campbell, "[t]he claimed invention of Stice...would not render obvious the claimed invention of Campbell, because the claimed invention of Stice, which uses as the donor cell a proliferating (and thus unsynchronized) cell, would not suggest synchronizing the proliferating cells, as required by the claimed invention of Campbell, and use instead an isolated diploid cell in the G1 phase" (Paper 22 at 19). Thus, Stice's argument appears to be that it would not have been obvious to select a cell in the G1 phase of the cell cycle from a disclosure of a cell in either the M, G1, S, or G2 phase of the cell cycle.

To support its position, Stice points to a portion of the declaration testimony of Dr. Piedrahita where Piedrahita concludes that "the claimed invention of Stice, which uses as donor cells proliferating (and unsynchronized) cells, would not suggest a method, like Campbell's

method, in which G1 cells are isolated (most likely through synchronization), and then used as the donor cells." (Exh. 2002 at 31). Dr. Piedrahita's observation that proliferating and G1 cells are not literally the same, is not a sufficient basis for concluding that the selection of a G1 donor cell would not have been obvious in view of a disclosure of a proliferating donor cell. Opinions expressed without disclosing the underlying facts may be given little, or no, weight. *See Rohm and Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092, 44 USPQ2d 1459, 1462 (Fed. Cir. 1997) (nothing in the Federal Rules of Evidence or Federal Circuit jurisprudence requires the fact finder to credit the unsupported assertions of an expert witness). As Dr. Piedrahita has not adequately explained the basis for his opinion, we do not find his testimony persuasive.

Stice has not shown that the donor cell type is a sufficient basis for a determination of no interference-in-fact.

The "without activation for a sufficient time" limitation:

Stice argues that the Campbell claims require a step of maintaining the reconstructed embryo "without activation for a sufficient time to allow the reconstructed embryo to become capable of developing to term." According to Stice, Campbell achieves the step by using a calcium free medium.

None of Campbell's claims require a calcium free medium. Nonetheless, Dr. Piedrahita testified that "the only teaching Campbell provides for delaying activation during the 'maintaining' step (ii) is to incubate the reconstructed embryo in a calcium-free medium." Dr. Piedrahita testified that, in contrast to the Campbell specification, the Stice specification describes the use of a medium that contains calcium ions. (FF 46).

The Campbell specification states that (FF 51):

> In a preferred embodiment of the invention, fusion of the oocyte karyoplast couplet is accomplished in the absence of activation by electropulsing in 0.3M mannitol solution or 0.27M sucrose solution; alternatively the nucleus may be introduced by injection in a calcium free medium. The age of the oocyte at the time of fusion/injection and the absence of calcium ions from the fusion/injection medium prevent activation of the recipient oocyte.

According to Stice, its claims would not have anticipated or rendered obvious the Campbell claims "because the Stice invention does not teach or suggest maintaining the nuclear transfer (NT) unit 'without activation' (as defined by Campbell, by using a calcium-free medium) after fusion and prior to the activation step" (Paper 22 at 21).

Stice does not sufficiently explain why we should read Campbell's claims as requiring the use of a particular medium. It is improper to read an extraneous limitation from the specification into the claims unless there is reasons to do so, e.g.., to interpret particular words or phrases in the claim. *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994).

Nonetheless, even if we turn to Campbell's specification, we do not see where a calcium containing medium is described as the only means for delaying activation. The portion of the Campbell specification that Stice relies upon to show the use of calcium free medium (at FF 51) describes the medium used for the transfer procedure and not the medium for the reconstructed embryo. According to Campbell's specification the reconstructed embryo is "returned to the maturation medium [and] is maintained without being activated" (FF 52). Dr. Wells testified that he is familiar with the maturation medium described in the Campbell specification, i.e., "TC

medium 199 with Earles salts (Gibco)", and that the medium contains calcium. (FF 53). Stice does not dispute Dr. Wells' testimony in its reply.[11]

Stice has not sufficiently explained why Campbell's claim requirement of some delay in activation would not have been rendered obvious by the Stice claims. In particular, we note that Stice claims 3 and 6 require a separate activation step such that there would be at least some time between formation of the reconstructed embryo and activation. (FFs 12 (b) and (e)).

Stice also has not sufficiently explained why the Campbell claims requiring a delay in activation would not have anticipated or rendered obvious the Stice claims which also require a time between formation of the reconstructed embryo and activation. Stice relies upon its argument that the specifications of Stice and Campbell describe different mediums for the reconstructed embryos. However, when we consider the evidence pointed out to us, we are not persuaded that the reconstructed embryo medium described by Campbell lacks calcium. Nonetheless, even if we were to accept Stice's argument, Stice has not explained why we should interpret the claims as requiring the use of any particular medium described in Stice's or Campbell's specifications.

Accordingly, Stice has not shown that the delay in activation limitation is a sufficient basis for our determining that the Stice and Campbell claims do not interfere-in-fact.

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[11] Stice suggests that the Campbell claims lack an enabling disclosure since Dr. Wells testified that the maturation medium "does not result in activation of most reconstructed embryos." (Paper 57 at 9-10). Stice did not move under 37 CFR § 1.633(a) based on Campbell's lack of an enabling disclosure and we do not consider whether Dr. Wells' testimony shows that Campbell claims lack an enabling disclosure.

As Stice has not shown that its and Campbell's claims define separately patentable inventions, Stice preliminary motion 1 is DENIED.

D. Campbell preliminary motion 1

In its preliminary motion 1, Campbell moves to substitute proposed count 4 for Counts 1 through 3. Stice does not oppose. As the moving party, Campbell has the burden of proof to show that it is entitled to the relief sought in its motion. 37 CFR § 1.637(a). "The fact that a motion is unopposed does not act to relieve a party from the burden of proof imposed on all parties filing motions by 37 CFR § 1.637(a)." *GN v. SW*, 57 USPQ2d 1073, 1076 (BPAI 2000).

Proposed count 4 is essentially a combination of Counts 1 through 3. Proposed count 4 reads as follows (FF 56):

> A method according to any of claims 1, 2, 3, 4, 5, or 6 of Stice patent 5,945,577, where the 'non-human mammal' is a bovine, ovine, or porcine and where the 'non-human mammalian fetus' is a bovine, ovine or porcine fetus, or a method according to any of claims 19, 23, 27, 31, 35, 39, 43, 47, or 51 [footnote omitted] of Campbell application 09/650,194 [footnote omitted], where the 'non-human mammal' is a bovine, ovine, or porcine and where the 'non-human mammalian fetus' is a bovine, ovine, or porcine fetus.

As the moving party, Campbell has the burden of explaining, *inter alia*, why the interfering subject matter should be redefined by substituting proposed count 4 for Counts 1 through 3. 37 CFR § 1.637(c). According to Campbell, it is appropriate to redefine the interfering subject matter by substituting proposed count 4 for Counts 1 through 3, since Counts 1 through 3 do not define separately patentable subject matter (Paper 28 at 4).

Campbell argues that neither the parties nor the examiner consider the cloning methods defined by Counts 1 through 3 to be separately patentable. In particular, Campbell argues that:

(1) the cloning methods claimed by Campbell and Stice are identical for all species claimed (Paper 28 at 5-8).

(2) neither the Campbell nor the Stice specification draws a distinction between the species of animals produced (Paper 28 at 5-8).

(3) the examiner made no restriction requirement between the species claimed in either the Campbell or Stice application during *ex parte* prosecution (Paper 28 at 8).

(4) the examiner rejected Stice claims for obviousness-type double patenting on the basis that claims to cloning "mammals" were not separately patentable over claims to cloning "pigs" (Paper 28 at 8-9).

(5) During *ex parte* prosecution, Stice argued that its invention was "generic" and that the cloning methods it described could be used to clone mammals other than bovines (Paper 28 at 9).

In support of its position, Campbell relies upon:

(1) its assertion that the Campbell and Stice specifications and claims do not treat the species of Counts 1 through 3 as being patentably distinct, and

(2) its assertion that, during *ex parte* prosecution, neither the examiner nor Stice treated the species of Counts 1 through 3 as being patentably distinct.

Even if Campbell's assertions are correct, they do not provide evidence sufficient to show that the species of Counts 1 through 3 are not patentably distinct from one another.

Campbell's reliance on its own or Stice's specification to show that the methods of Counts 1 through 3 are the same patentable invention is improper. It is the claims, and not the specifications, of each party that define the interfering subject matter and thus what is potential

prior art to the other party. Thus it is the claims, not the specifications, that are available to show whether or not two inventions are separately patentable. *Noelle v. Lederman*, 355 F.3d 1343, 1352, 69 USPQ2d 1508, 1516 (Fed. Cir. 2004).

Campbell notes that each party is claiming the same nuclear transfer method for use in bovine, ovine, and porcine animals, i.e., the animals of Counts 1 through 3, respectively. It is not apparent to us, and Campbell has not explained sufficiently, how the fact that a party claims the same method to produce different animals establishes that it was obvious to use the same method to produce each animal at the time the methods were invented.

Campbell argues that the examiner treated the species of Counts 1 through 3 as the same patentable invention by, e.g., failing to make restriction requirements and by making an obviousness type double patenting rejection.

At the outset, we note that we are not bound by the *ex parte* actions of the examiner. *Glaxo Wellcome Inc. v. Cabilly*, 56 USPQ2d 1983, 1984 (BPAI 2000). Nonetheless, it is our understanding that the examiner has discretion in deciding whether or not to require election[12] between claims directed to separately patentable species. 37 CFR § 1.146. Thus, the examiner's failure to require an election of species does not establish that the examiner determined the subject matter of Counts 1 through 3 to be directed to the same patentable invention.

Moreover, the fact that Stice's claims to methods of cloning mammals may have been rejected by the examiner as being obvious over Stice's copending claims to methods of cloning

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[12] Where separately patentable species are claimed, it may be appropriate to require election of a single species for initial examination. 37 CFR § 1.146. A restriction requirement is appropriate where independent and distinct inventions are claimed. 37 CFR § 1.142.

pigs as Campbell argues (Paper 28 at 8-9) does not show that the examiner considered the species of Count 1 through 3 to be directed to the same patentable invention. It is not clear from the examiner's actions that the examiner considered the limitation of "mammal" to have anticipated or rendered obvious the limitation of "pig" since generally, a 'one-way' test is applied to determine obviousness-type double patenting. *In re Berg*, 140 F.3d 1428, 1432, 46 USPQ2d 1226, 1229 (Fed. Cir. 1998). Thus, if the examiner found that the limitation of "pig" anticipated the limitation of "mammal" the examiner's actions as described by Campbell, would seem to have been appropriate.

Campbell points to Stice's actions during *ex parte* prosecution to show that Stice considered the subject matter of Counts 1 through 3 to be directed to the same patentable invention. However, Stice's actions during *ex parte* prosecution of its involved application as described by Campbell do not amount to sufficient evidence to show the claims to be separately patentable. Stice's statement that its invention was generic and could be used in various mammals does not seem to relate to whether Counts 1 through 3 define the same patentable invention. It is our understanding that Stice's statement was made in an effort to rebut the examiner's position that Stice was not enabled for the full scope of its claims. It is not apparent to us, and Campbell has not adequately explained, how Stice's arguments that it was enabled for the full scope of its claims establishes that the subject matter of Counts 1 through 3 is directed to the same patentable invention.

The counts set forth in the Notice Declaring Interference are presumed to be correct counts and it is Campbell's burden to rebut that presumption. Since Campbell has not met its burden, Campbell preliminary motion 1 is DENIED.

E. Campbell preliminary motion 3

In its preliminary motion 3, Campbell moves for judgment that the Stice claims are unpatentable for failing to comply with the written description requirement of 35 USC § 112, ¶ 1. As the moving party, Campbell has the burden of proof to show that it is entitled to the relief sought in its motion. 37 CFR § 1.637(a). We GRANT Campbell preliminary motion 3.

In order to meet the written description requirement the specification must clearly convey to those skilled in the art that the applicant invented the claimed subject matter. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1562-63, 19 USPQ2d at 1116 (Fed. Cir. 1991). "Although the exact terms need not be used in *haec verba*, . . . the specification must contain an equivalent description of the claimed subject matter. A description which renders obvious the invention . . . is not sufficient." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The Stice specification indicates that the novelty of the invention lies in the use of a differentiated cell as the donor cell. (FF 62). During *ex parte* prosecution of the Stice application, all of Stice's claims were amended to require the use of a donor cell that is a "proliferating somatic cell that has been expanded in culture" (Paper 30 at 13 and Paper 51 at 2). Thus, the involved Stice claims require not only a somatic[13] donor cell, but a donor cell that is in the G1, S, G2, or M phase of the cell cycle, i.e., proliferating (FF 65), and not in the G0 phase of the cell cycle. (FF 66).

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[13] There seems to be no dispute between the parties that differentiated cells are somatic cells.

Campbell argues that "[t]here is no literal, equivalent, or inherent support" for the use of a donor cell that is "proliferating" within the Stice specification. We agree with Campbell that there is no literal support for the use of a proliferating donor cell in that Stice does not use the term "proliferating" to describe its donor cell. Nonetheless, *ipsis verbis* support is not necessary if the disclosure otherwise reasonably conveys to one skilled in the art that the inventor had possession of the subject matter in question. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

According to Campbell there is no instruction in the Stice specification to select a donor cell that is proliferating instead of non-proliferating. (Paper 30 at 17). Campbell acknowledges that Stice's example 1 describes culturing fibroblasts for use as donor cells and that some of the fibroblasts would be in the M, G1, S, or G2 phase of the cell cycle, and that some of the fibroblasts would be in the G0 phase of the cell cycle. In particular, Campbell witness Dr. Wells testified that (FF 77) :

> Based on my experience using proliferating cultured fibroblasts in various phases of the cell cycle, proliferation is not a process that all fibroblasts in culture inherently undergo at all stages of their lifecycle. Fibroblasts cells can be proliferating or non-proliferating. Fibroblast cells can be in the M, G_1, S, G_2 phase of the cell cycle, or in the G_0 state.

Stice argues that "[c]ells that are proliferating in culture are unsynchronized and thus can exist in any of the four phases of the cell cycle-G1, S, G2, or M." Stice does not specifically state, and the evidence pointed out to us does not indicate, that all the fibroblasts in the CL-1 cell line described in example 1 of the Stice specification would be proliferating. For example, Stice witness Dr. Piedrahita testified that "[i]n a proliferating cell population such as that described in Example 1, most of the fibroblasts .....should be G1 phase fibroblasts". (FF 72(c)). In support of

his testimony, Dr. Piedrahita pointed to an article by Boquest. The Boquest article indicates that the proliferating cultures contained fibroblasts in all phases of the cell cycle, with the majority being in the G1 phase (FF 75). The article shows that a small percentage of fibroblasts in the proliferating culture (i.e., 2.8 ± 1.2) were in the G0 phase of the cell cycle and thus are cells that Stice describes as not proliferating (FF 76). The Boquest article is consistent with Dr. Wells' testimony that fibroblasts in culture are not inherently proliferating. To the extent Dr. Piedrahita's and Dr. Well's testimony is inconsistent regarding whether a fibroblast in culture is inherently proliferating, we credit Dr. Wells' testimony that a fibroblast in culture is not inherently proliferating.

The evidence before us indicates that it is likely that most of the cells found in the CL-1 cell line of Stice example 1 were proliferating cells. However, "inherency cannot be established by probabilities of possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981). The donor cell described by Stice is not inherently a proliferating cell since the cells described by Stice may or may not be proliferating. While it may be that it would have been obvious to select a proliferating cell within the differentiated donor cells described, obviousness is not the standard for written description. *Lockwood v. American Airlines*, 107 F.3d at 1572, 41 USPQ2d at 1966 (Fed. Cir. 1997).

Stice argues that Campbell "admits that Example 1 describes 'a proliferating somatic cell [fibroblast] that has been expanded in culture'" (Paper 51 at 13). Campbell's statements that a given cell in culture will stop proliferating under certain conditions seem to recognize that most

cells in culture are proliferating at any given time. However, we do not think that Campbell's statements amount to an admission that all cells in culture are proliferating at all times.

Stice argues that its specification does not teach how to induce quiescence in a population of cells and thus would not lead one to a G0 cell (Paper 51 at 11). We agree with Stice to the extent that nothing we have been directed to in the specification suggests that the donor cell should be quiescent. On the other hand, nothing we have been directed to in the Stice specification suggests that the donor cell should be proliferating. Thus, Stice's specification does not clearly convey that Stice was in possession of a nuclear transfer method wherein a proliferating cell, in particular, should be used as the donor cell.

In its preliminary motion, Campbell suggests that Stice amended its claims to include the "proliferating" limitation in response to work done by Campbell (Paper 30 at 3-4 and 11).[14] It is not clear to us, and Campbell has not explained, why Stice's reason for amending its claims is relevant to whether Stice sufficiently described the claimed invention. We do not base our decision upon what Campbell suggests as Stice's reasoning for amending its claims but upon whether or not Stice's involved claims are supported. We find that Stice's claims are not adequately supported under 35 USC § 112, ¶ 1. Accordingly, we GRANT Campbell preliminary motion 3.

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[14] For example, Campbell argues that the cloning of "Dolly" the sheep by the Campbell inventors was reported in *Nature* (Wilmut et al., *Nature*, 385:810-813, (1997)(Exh. 1032)), and involved the use of a quiescent differentiated donor cell in the nuclear transfer method of cloning (Paper 30 at 3).

F. Campbell preliminary motion 4

In its preliminary motion 4 Campbell moves for judgment that the Stice claims are unpatentable under 35 USC § 112, ¶1, for lack of an enabling disclosure. Because we GRANT Campbell's preliminary motion 3 and find Stice's claims to be unpatentable for lack of written description support, we need not and do not determine if Campbell's claims are also unpatentable based on a lack of an enabling disclosure. Campbell preliminary motion 4 is DISMISSED as moot.

G. Campbell preliminary motions 5 through 7

In its preliminary motion 5, Campbell moves to add claims 52 through 84 to its involved application. Campbell's motion is said to be responsive to Stice's preliminary motions 1 through 3 filed under 37 CFR § 1.633(a) and (b). Since Stice preliminary motions 1 through 3 are DENIED, we DISMISS as moot Campbell preliminary motion 5.

Campbell preliminary motions 6 and 7 are contingent upon our granting Campbell preliminary motion 5. Since we DISMISS Campbell preliminary motion 5, Campbell preliminary motions 6 and 7 are also DISMISSED as moot.

H. Campbell preliminary motion 2

Campbell moves to be accorded priority benefit of United Kingdom patent application GB 9517779.6 ("the GB application), filed 31 August 1995 for Counts 1 through 3.[15] Counts 4 through 6 are substituted for Counts 1 through 3. Nonetheless, we consider the Campbell

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[15] Campbell's preliminary motion 2 is unclear in that it also refers to Campbell proposed count 4. We understand Campbell to be moving for priority benefit as to **either** Counts 1 through 3 **or**, contingent on the granting of its preliminary motion to substitute Campbell proposed count 4, Campbell proposed count 4 (see e.g., Paper 29 at 4).

preliminary motion and the Stice opposition to the extent they are relevant to whether Campbell should be given priority benefit of the GB application for the subject matter of Counts 4 through 6.

A single described enabled embodiment within the scope of the count is sufficient for priority benefit. *Hunt v. Treppschuh*, 523 F.2d 1386, 1389, 187 USPQ 426, 429 (CCPA 1975). The GB application is substantially the same as Campbell's involved application. (FF 79). Campbell has shown where, in its GB application, support is provided for each of its claims and thus the subject matter of Counts 4 through 6. (See Exh. 1017).

Stice argues that the GB application does not provide written description support for the subject matter of the Counts. Stice's arguments are substantially the same as the arguments it made in its preliminary motion 2. (FF 81). Stice's arguments are unpersuasive here for the same reasons that they were unpersuasive in its preliminary motion 2.

Campbell preliminary motion 2 is GRANTED with respect to Counts 4 through 6.

I. Order

Upon consideration of the record and for reasons given, it is

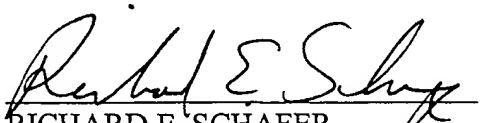
ORDERED that Stice preliminary motions 1 through 3 are DENIED;

FURTHER ORDERED that Campbell preliminary motion 1 is DENIED;

FURTHER ORDERED that Campbell preliminary motions 2 and 3 are GRANTED;

FURTHER ORDERED that Campbell preliminary motions 4 through 7 are DISMISSED as moot; and

FURTHER ORDERED that the interference will be redeclared in a separate paper in accordance with this decision.



RICHARD E. SCHAFER
Administrative Patent Judge)
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RICHARD TORCZON) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
) INTERFERENCES
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Paper 110

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

NIKOLAI S. **STRELCHENKO**,
JEFFREY M. BETTHAUSER,
GAIL L. JURGELLA, MARVIN M. PACE,
and MICHAEL D. BISHOP
(Application 09/357,445),

v.

KEITH HENRY STOCKMAN **CAMPBELL**
and IAN WILMUT,
Senior Party,
(Application 09/650,194).

Patent Interference No. **104,809**

Before SCHAFER, TORCZON, and LANE, Administrative Patent Judges.
LANE, Administrative Patent Judge.

JUDGMENT PURSUANT TO 37 CFR § 1.662

Strelchenko has filed a paper stating that it "abandons the contest and will take no further action in this interference." (Paper 109 at 1). Strelchenko's statement that it is abandoning the contest is treated as a request for adverse judgment against Strelchenko as to all its claims that correspond to the counts of the interference. 37 CFR § 1.662(a).

Upon consideration of the record of the interference, it is

ORDERED that judgment as to Counts 4 through 6 is awarded against junior party NIKOLAI S. STRELCHENKO, JEFFREY M. BETTHAUSER, GAIL L. JURGELLA, MARVIN M. PACE, and MICHAEL D. BISHOP;

FURTHER ORDERED that junior party NIKOLAI S. STRELCHENKO, JEFFREY M. BETTHAUSER, GAIL L. JURGELLA, MARVIN M. PACE, and MICHAEL D. BISHOP, is not entitled to a patent containing claims 57, 58, 61-63, 69-88, 106, 112-115, and 118, which correspond to each of Counts 4 through 6;

FURTHER ORDERED that if there is a settlement agreement, the parties' attention is directed to 35 USC § 135(c); and

FURTHER ORDERED that a copy of this decision be given a paper number and be entered in the administrative records of Strelchenko's 09/357,445 application and Campbell's 09/650,194 application.

RICHARD E. SCHAFER
Administrative Patent Judge

RICHARD TORCZON
Administrative Patent Judge

SALLY GARDNER LANE
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES

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Paper 106

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Filed
6 January 2004

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES
(Administrative Patent Judge Sally Gardner Lane)

NIKOLAI S. **STRELCHENKO**,
JEFFREY M. BETTHAUSER,
GAIL L. JURGELLA, MARVIN M. PACE,
and MICHAEL D. BISHOP
(Application 09/357,445),

v.

KEITH HENRY STOCKMAN **CAMPBELL**
and IAN WILMUT,
Senior Party,
(Application 09/650,194).

Patent Interference No. **104,809**

Before: SCHAFER, TORCZON, and LANE, Administrative Patent Judges.

LANE, Administrative Patent Judge.

DECISION ON MOTIONS

I. Introduction

The interference was declared on 6 March 2002 between junior party Nikolai S. Strelchenko, Jeffrey M. Betthauser, Gail L. Jurgella, Marvin M. Pace, and Michael D. Bishop ("Strelchenko") and senior party Keith Henry Stockman Campbell and Ian Wilmut ("Campbell"). An oral hearing on the preliminary motions was held on 25 September 2003.[1]

Background

Strelchenko was a party in related interference 104,808 ("'808"). The '808 interference, like the present interference, involved all the claims of Strelchenko's 09/357,445 application. In the '808 interference, all of Strelchenko's claims were held to be unpatentable to Strelchenko under 35 USC § 135(b). Consequently, the '808 interference was terminated.

Accordingly, all the Strelchenko claims that were designated as corresponding to the counts of the present interference are unpatentable to Strelchenko.[2] In its preliminary motion 4, Strelchenko moves to add two claims to its involved application and have the claims designated as corresponding to one or more of the counts of the interference (Paper 60).

Brief summary of the involved technology

Campbell's claims are directed to methods of cloning using a procedure known as nuclear transfer. Many of Campbell's claims are limited to cloning an ungulate animal (e.g., cow, sheep, and pig). However, some of Campbell's claims are directed to cloning a "non-human mammal".

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[1] George Quillin represented Strelchenko and Kenneth Meyers and David Earp represented Campbell.

[2] At oral hearing, Mr. Quillin confirmed that no judicial review of the '808 decision is pending (Paper 108 at 6:3-9).

Nuclear transfer involves, *inter alia*, transferring the nucleus of a donor cell into an enucleated oocyte to form a reconstructed embryo. The Campbell claims require that the donor cell be a cultured diploid differentiated cell, such as a fibroblast, in the G1 phase of the cell cycle. The Campbell claims also require that, after nuclear transfer, the reconstructed embryo be maintained "without activation for a sufficient time to allow the reconstructed embryo to become capable of developing to term".

The claims that Strelchenko proposes to add to its involved application ("the proposed claims") are also directed to methods for cloning an ungulate animal using nuclear transfer. However, the proposed claims require that a reprogramming step be undertaken prior to nuclear transfer. In the reprogramming step a precursor cell is said to be converted into a totipotent cell that then acts as the donor cell for nuclear transfer. None of the Campbell claims requires a reprogramming step prior to nuclear transfer and none of the Campbell claims uses a totipotent cell as the donor cell.

The level of skill in the art may be inferred from the references of record and the background of the witnesses, *In re GPAC*, 57 F.3d 1573, 1579, 35 USPQ2d 1116, 1121 (Fed. Cir. 1995); *Enzo Biochem., Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1373, 52 USPQ2d 1129, 1137 (Fed. Cir. 1999).

Summary of the decision

We DENY Strelchenko motion 2 and Strelchenko preliminary motions 3 and 4.

We DENY Campbell preliminary motions 2 and 8.

We GRANT Campbell preliminary motions 4 and 5.

We DISMISS as moot Campbell preliminary motions 1, 3, 6, 7, and 9 through 12.

We redeclare the interference with the following changes:

(1) Counts 4 through 6 are substituted for Counts 1 through 3,

(2) Campbell is accorded priority benefit of its United Kingdom patent application GB 9517779.6 for the subject matter of the substitute counts, and

(3) Strelchenko is not accorded priority benefit of its 08/812,851 application for the subject matter of the substitute counts.

II. Findings of fact

The record supports the following findings of fact as well as any other findings of fact set forth in any other portion of the decision by at least a preponderance of the evidence.

The interference

1. Strelchenko is involved in the interference on the basis of its 09/357,445 ("'445") application, filed 20 July 1999.
2. According to Strelchenko, its real party in interest is Infigen, Inc. (Paper 10).
3. Campbell is involved in the interference on the basis of its 09/650,194 ("'194") application, filed 29 August 2000.
4. According to Campbell, its real party in interest is (1) Assignees: Department for Environment, Food & Rural Affairs of London, England and Roslin Institute (Edinburgh) of Midlothian, England; (2) licensees: Geron Corporation, of Menlo Park, CA and PPL Therapeutics Ltd of Midlothian, England (Paper 5).

The counts

5. The interference was declared with three counts: Count 1, Count 2, and Count 3.

6. **Count 1** is as follows (Paper 1 at 5):

> A method according to either of claims 57 or 106 of Strelchenko application 09/357,445, wherein the ungulate animal is a bovine
>
> or
>
> a method according to any of claims 19 or 23 of Campbell application 08/803,165.[3]

7. **Count 2** is as follows (Paper 1 at 6):

> A method according to either of claims 57 or 106 of Strelchenko application 09/357,445, wherein the ungulate animal is an ovine,
>
> or
>
> a method according to any of claims 27 or 31 of Campbell application 08/803,165.

8. **Count 3** is as follows (Paper 1 at 7):

> A method according to either of claims 57 or 106 or Strelchenko application 09/357,445, wherein the ungulate animal is a porcine,
>
> or
>
> a method according to any of claims 35 or 39 or 43 or 47 of Campbell application 08/803,165, where the "non-human mammal" is a pig or porcine and where the "non-human mammalian fetus" is a pig fetus or a porcine fetus.

9. Strelchenko claim 57 is as follows:

> A method for preparing an ungulate animal, said method comprising:
>
> a) obtaining a cell from an ungulate fetus;
>
> b) culturing said cell to form a cell culture;

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[3] As noted by Campbell (e.g., Paper 42 at 3 (fn. 1)), each of Counts 1 through 3 incorrectly refers to the parent of the involved Campbell application. The Campbell application referred to in Counts 1 through 3 should be the involved Campbell application, i.e., 09/650,194.

c) forming a cybrid by nuclear transfer of a cell obtained from said cell culture, or a nucleus thereof into an enucleated oocyte obtained from the same species as the cell in step (a); and

d) culturing said cybrid so as to generate an embryo comprising embryonic cells; and

e) transferring said embryo of step (d) or a recloned embryo of said embryo of step (d) into the uterus of an ungulate of the same species as the cell in step (a) so as to produce a fetus that undergoes full fetal development and parturition to generate said ungulate animal.

10. Strelchenko claim 106 is as follows:

A method for preparing an ungulate animal, said method comprising;

a) obtaining a non-embryonic cell from an ungulate;

b) culturing said non-embryonic cell to form a cell culture, wherein said cell culture is not serum starved;

c) forming a cybrid by nuclear transfer of a cell obtained from said cell culture, or a nucleus thereof into an enucleated oocyte obtained from the same species as the cell in step (a);

d) culturing said cybrid so as to generate an embryo comprising embryonic cells; and

e) transferring said embryo of step (d) or a recloned embryo of said embryo of step (d) into the uterus of an ungulate of the same species as the cell in step (a) so as to produce a fetus that undergoes full fetal development and parturition to generate said ungulate animal.

11. Claim 19 of Campbell is as follows:

A method of cloning a cow by nuclear transfer comprising:

(i) inserting a nucleus of a cultured diploid bovine fibroblast in the G1 phase of the cell cycle into an unactivated, enucleated metaphase II-arrested bovine oocyte to reconstruct an embryo;

(ii) maintaining the reconstructed embryo without activation for a sufficient time to allow the reconstructed embryo to become capable of developing to term;

(iii) activating the resultant reconstructed embryo;

(iv) culturing said activated, reconstructed embryo to blastocyst; and

(v) transferring said cultured, reconstructed embryo to a host cow such that the reconstructed embryo develops to term.

12. The other Campbell claims referred to in the counts are also directed to a method of cloning by nuclear transfer comprising the same steps as Campbell claim 19. The following differences are noted:

(a) Campbell claim 23 is directed to a method of cloning a bovine fetus.

(b) Campbell claim 27 is directed to a method of cloning a sheep.

(c) Campbell claim 31 is directed to a method of cloning an ovine fetus.

(d) Campbell claim 35 is directed to a method of cloning a non-human mammal.

(e) Campbell claim 39 is directed to a method of cloning a non-human mammalian fetus.

(f) Campbell claim 43 is directed to a method of cloning a non-human mammal and requires that the donor cell be a differentiated cell.

(g) Campbell claim 47 is directed to a method of cloning a non-human mammalian fetus and requires that the donor cell be a differentiated cell.

Claim correspondence

13. The following claims were designated as corresponding to **Count 1** (Paper 1 at 5):

Strelchenko: 57-58, 61-63, 69-88, 106, 112-115, and 118

Campbell: 19-26 and 35-50

14. The following claims were designated as corresponding to **Count 2** (Paper 1 at 6):

Strelchenko: 57-58, 61-63, 69-88, 106, 112-115, and 118

Campbell: 27-50

15. The following claims were designated as corresponding to **Count 3** (Paper 1 at 7):

Strelchenko: 57-58, 61-63, 69-88, 106, 112-115, and 118

Campbell: 35-51[4]

16. All the Strelchenko claims designated as corresponding to Counts 1 through 3 were held to be unpatentable to Strelchenko under 35 USC § 135(b). *Strelchenko v. University of Massachusetts*, (Interference 104,808, Paper 88 at 30), http://www.uspto.gov/web/offices/dcom/bpai/its/104808-088.pdf, (BPAI 2003).

Benefit

17. Strelchenko was accorded priority benefit of the following two applications for all three counts of the interference (Paper 1 at 3):

> US application 09/239,922, filed 28 January 1999 and issued as patent 6,011,197 on 4 January 2000, and
>
> US application 08/812,851 ("'851"), filed 6 March 1997.

18. Campbell was accorded priority benefit of the following two applications for all three counts of the interference (Paper 1 at 2):

> US application 08/803,165, filed 19 February 1997 and issued as patent 6,252,133 on 26 June 2001, and

---

[4] Campbell was authorized to file an amendment adding claim 51 to its involved application (Paper 17 at 3). Campbell claim 51 is directed to a method of cloning a pig using the nuclear transfer method and thus corresponds to Count 3 (Paper 23 at 10).

PCT application PCT/GB96/02098, filed 30 August 1996.

Strelchenko motions

19. Strelchenko filed the following motions:

(a) Strelchenko preliminary motion 1 under 37 CFR § 1.633(b) for a judgment that there is no interference-in-fact (Paper 24).

(b) Strelchenko motion 2 under 35 CFR § 1.635 requesting permission to file a motion to declare additional interferences between the '445 application and Campbell patents (Paper 25).[5]

(c) Strelchenko preliminary motion 3 under 37 CFR § 1.633(a) seeking judgment that the involved Campbell claims are unpatentable under 35 USC § 112, ¶ 1 (Paper 50).

(d) Strelchenko preliminary motion 4 under 37 CFR § 1.633(c)(2) seeking to add proposed claims to the '445 application (Paper 60).

20. Strelchenko preliminary motion 1 was denied (Paper 52).

21. Strelchenko did not request reconsideration under 37 CFR § 1.640(c) of the decision denying its preliminary motion 1.

Campbell motions

22. Campbell filed the following motions:

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[5] Strelchenko motion 2 is unopposed.

(a) Campbell preliminary motion 1 under 37 CFR § 1.633(a) seeking judgment that the Strelchenko claims are unpatentable under 35 USC § 135(b) (Paper 21).

(b) Campbell preliminary motion 2 under 37 CFR § 1.633(c)(5) seeking to require Strelchenko to add proposed claims to its '445 application (Paper 29).

(c) Campbell preliminary motion 3 under 37 CFR § 1.633(c)(1) seeking to substitute proposed count 4 for Counts 1 through 3 (Paper 30).

(d) Campbell preliminary motion 4 under 37 CFR § 1.633(f) seeking to be accorded priority benefit of earlier filed applications (Paper 31).

(e) Campbell preliminary motion 5 under 37 CFR § 1.633(g) seeking to deny Strelchenko priority benefit of the filing date of Strelchenko's '851 application (Paper 39).

(f) Campbell preliminary motion 6 under 37 CFR § 1.633(a) seeking judgment that the involved Strelchenko claims are unpatentable under 35 USC § 112, ¶ 1 (Paper 40).

(g) Campbell preliminary motion 7 under 37 CFR § 1.633(a) seeking judgment that the involved Strelchenko claims are unpatentable under 35 USC §§ 102 and 103 (Paper 41).

(h) Campbell preliminary motion 8 under 37 CFR § 1.633(c)(1) seeking to substitute proposed count 5 for Counts 1 through 3 (Paper 42).

(i) Campbell preliminary motion 9 under 37 CFR § 1.633(a) seeking judgment that the involved Strelchenko claims are unpatentable 35 USC § 112, ¶2 (Paper 43).

(j) Campbell preliminary motion 10 under 37 CFR § 1.633(c)(2) seeking to add claims to the '194 application (Paper 55).[6]

(k) Campbell preliminary motion 11 under 37 CFR § 1.633(c)(1) seeking to substitute proposed Count 6 for Counts 1 through 3 (Paper 56).

(l) Campbell preliminary motion 12 under 37 CFR § 1.633(f) seeking to be accorded priority benefit of the filing date of earlier filed applications as to proposed count 6 (Paper 57).

Campbell preliminary motion 2 and Strelchenko preliminary motion 4

23. In its preliminary motion 2, Campbell seeks to require Strelchenko to add proposed claims 119 and 120 to its '445 application.

24. Campbell indicated that its preliminary motion 2 is filed as a responsive motion under 37 CFR § 1.633(i) in that Campbell wishes to add claims to the '445 application, in the event Strelchenko's preliminary motion 1 for a judgment of no-interference-in-fact is granted (Paper 29 at 1).

25. In its preliminary motion 4, Strelchenko seeks to add proposed claims 119 and 120 to its '445 application.

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[6] At the oral hearing, counsel for Campbell confirmed that its preliminary motion is contingent in that claims 52 through 84 need not be added to its application if Strelchenko preliminary motion 3 is denied (Paper 108 at 34:8-12).

26. According to Strelchenko, its preliminary motion 4 is filed in response to Campbell preliminary motion 2 and Campbell preliminary motion 6 filed under 37 CFR § 1.633(a) seeking judgment that the Strelchenko involved claims are unpatentable to Strelchenko for lack of an enabling disclosure (Paper 60 at 1 and 15).

27. Campbell has filed an opposition to Strelchenko preliminary motion 4 and Strelchenko has filed an opposition to Campbell preliminary motion 2.[7]

28. Proposed claim 119 is as follows (Paper 29 at 2-3 and Paper 60 at 3):

A method for preparing an ungulate animal, said method comprising:
(a) obtaining a primordial germ cell from an ungulate fetus;
(b) reprogramming said primordial germ cell to form a reprogrammed cell by cultivation in a culture medium;
(c) forming a cybrid by nuclear transfer of said reprogrammed cell into an enucleated ungulate oocyte of the same species, wherein said oocyte[8] is matured for about 16 to about 28 hours to form a first polar body prior to enucleation, and wherein said reprogrammed cell is a proliferating cell that is 12-15 μm in size;
(d) activating said cybrid.

29. Proposed claim 120 is as follows (Paper 29 at 3 and Paper 60 at 3):

The method of claim 119, wherein the ungulate animal is a bovine animal.

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[7] Strelchenko opposition 2 states that Strelchenko does not oppose the relief sought by Campbell, only the facts and arguments set forth in Campbell preliminary motion 2 (Paper 62 at 2).

[8] Campbell's proposed claim 119 differs slightly from Strelchenko's proposed claim 119 in that it specifies that the oocyte is bovine. In view of the remainder of the claim and Campbell's arguments in its preliminary motion 2, it appears the specification of the oocyte as bovine in Campbell's proposed claim 119 is in error.

30. The proposed claims require a step (i.e., step (b)) wherein a "primordial germ cell" is reprogrammed prior to nuclear transfer.

31. According to the '445 specification, "[t]he term 'primordial germ cell' as used herein refers to a diploid somatic cell capable of becoming a germ cell" and that "[p]rimordial germ cells can be isolated from the genital ridge of a developing cell mass." (Exh. 1012 at 13:20-21).

32. The '445 specification states that, "[t]he term 'reprogramming' or 'reprogrammed' as used herein refers to materials and methods that can convert a non-totipotent cell into an [sic-a] totipotent cell." (Exh. 1012 at 12:17-18).

33. The '445 specification states that, "[t]he term 'totipotent' as used herein refers to a cell that gives rise to all of the cells in the developing cell mass, such as an embryo, fetus, and animal." (Exh. 1012 at 6:1-2).

34. The use of the term "totipotent" in the '445 specification is consistent with the ordinary meaning of the term. (See, e.g., Paper 37 at 10).

35. The '445 specification states that "[f]or example, a non-totipotent precursor cell can be converted into a totipotent cell" using a reprogramming step. (Exh. 1012 at 12:11-13).

36. The '445 specification states that (Exh. 1012 at 17:17-23):

> The term "differentiated cell" as used herein refers to a precursor cell that has developed from an unspecialized phenotype to that of a specialized phenotype. For example, embryonic cells can differentiate into an epithelial cell lining the intestine. It is highly unlikely that differentiated cells revert into their precursor cell in vivo or in vitro. However, materials and methods of the invention can reprogram differentiated cells into immortalized,

totipotent cells. Differentiated cells can be isolated from a fetus or a live born animal, for example.

37. The use of the term"differentiated cell" in the '445 application is consistent with the ordinary meaning of the term. (See, e.g., Paper 37 at 4).

38. The '445 specification indicates that, while the prior art discloses nuclear transfer methods using totipotent embryonic cells, "[a] unique feature of the present invention is that immortalized, totipotent cells are reprogrammed from non-embryonic cells by utilizing the materials and methods described herein in descriptions of the preferred embodiments and exemplary embodiments." (Exh. 1012 at 17:28-18:2).

39. The '445 specification states that "[i]mmortalized, totipotent cells of the invention can be produced from virtually any type of precursor cell" such as "primordial germ cells arising from a developing mass (*e.g.*, genital ridge cells)." (Exh. 1012 at 49:10-18).

40. The '445 specification states that the immortalized, totipotent cells may be generated by exposing precursor cells to a stimulus. For example, a receptor ligand cocktail can be added to the culture medium to reprogram the precursor cells into immortalized, totipotent cells. (Exh. 1012 at 28:6-14 and 50:13-21).

41. It is the reprogrammed cell, and thus a totipotent cell, that acts as the donor cell in the nuclear transfer cloning method of proposed claims 119 and 120.

42. Campbell's claims are directed to a nuclear transfer cloning method wherein a differentiated cell, such as a fibroblast, acts as the donor cell.

43. A differentiated cell is not a totipotent cell. (Exh. 1012 at 17:17-18; See also Exh. 1017 at 21).

44. Because Campbell's involved claims do not require a totipotent donor cell, a reprogramming step prior to nuclear transfer is also not required

Strelchenko preliminary motion 3

45. According to Strelchenko, the '194 application does not provide sufficient written description as required by 35 USC § 112, ¶ 1, for the following (Paper 50 at 3-13).:

(a) the non-activation period required by element (ii) of the claims,

(b) a non-human mammalian donor cell in the G1 phase of the cell cycle,

(c) a nuclear transfer cloning method that does not require diploidy to be maintained by an active step, and

(d) the specific donor cell types in the G1 phase of the cell cycle.

46. According to Strelchenko, the '194 application did not enable one skilled in the art to make and use the full scope of the invention as required by 35 USC § 112, ¶ 1.

47. In particular, Strelchenko argues that the '194 specification was not enabling for the following limitations (Paper 50 at 15-24):

(a) the donor cell limitation, i.e., the requirement of the use of a fibroblast in the G1 phase of the cell cycle,

(b) the non-activation time period limitation required by element (ii) of the claims, and

(c) a nuclear transfer cloning method that does not require diploidy to be maintained by an active step

48. In support of its preliminary motion 3, Strelchenko relies upon the testimony of Dr. Erik J. Forsberg. (Exh. 2030).

The non-activation time period limitation:

49. Regarding the non-activation time period limitation, Dr. Forsberg testified that (Exh. 2030 at ¶ 15):

> The '194 application states that the purpose of this [non-activation time period limitation] requirement is to allow the donor nucleus to become exposed to the recipient cytoplasm. With regard to how this time period may be determined, the specification (SX2002) states at page 12, beginning at line 30:
>
> > The optimum period of time before activation varies from species to species and can readily be determined by experimentation. For cattle, a period of from 6 to 20 hours is appropriate. The time period should probably not be less than that which will allow chromosome formation, and it should not be so long either that the couplet activates spontaneously or, in extreme cases that it dies.

and that (Exh. 2030 at ¶ 16) :

> Except for the time range given for cattle, no other time range is disclosed anywhere in the '194 application. Because there is not a single working example in the '194 application that demonstrates any successful cloning method in which a non-human mammalian

cell in the G1 phase was used as the donor cell, there is also no example in the '194 specification where the time period described in the claims is shown to be correctly defined for the types of nuclear donor cells recited in the '194 application claims, either for bovines or for any other mammalian species.

50. Dr. Forsberg testified that, given the low success rate in nuclear transfer cloning methods, "the only way to identify an appropriate [non-activation] time was by trial and error, with the hope that some time might ultimately succeed in producing the desired result (a fetus or live-born animal) despite repeated failures with precisely the same conditions" and that "[t]he amount of experimentation called for is enormous." (Exh. 2030 at ¶ 17).

51. Dr. Forsberg testified that "there is virtually no guidance provided by the '194 application as to ... what might be an appropriate time that a reconstructed embryo, constructed using a G1 stage donor nucleus, should be maintained without activation..." (Exh. 2030 at ¶ 17),

52. The '194 specification states that an optimum non-activation time period "varies from species to species and can be readily determined by experimentation" and is a period that is long enough to allow for chromosome formation but not so long as to allow for spontaneous activation. (Exh. 1008 at 12:10-13:3).

<u>The donor cell limitation</u>:

53. Regarding the donor cell limitation, Dr. Forsberg testified that (Exh. 2030 at ¶ 11):

There is not a single working example in the '194 application that demonstrates any successful nuclear transfer cloning method in which a non-human mammalian cell in the G1 phase was demonstrably used as the donor cell. No description is provided as to how one might obtain a uniform population of G1 cells, or any methods by which G1 cells might be identified from a population of cells in all cell cycle stages, much less that any such methods had actually been performed by the applicants prior to August 31, 1995 (the earliest possible filing date for the '194 application) or prior to August 30, 1996 (the date of which the PCT application from which the '194 application claims benefit).

54. The '194 application states (Exh. 1008 at 8:9-17):

> The nuclei of quiescent G0 cells, like the nuclei of G1 cells, have a diploid DNA content; both of such diploid nuclei can be used in the present invention.
>
> Subject to the above, it is believed that there is no significant limitation on the cells that can be used in nuclear donors; fully or partially differentiated cells or undifferentiated cells can be used as can cells which are cultured *in vitro* or abstracted *ex vivo*.

55. The '194 application does not provide a procedure for isolating cells in the G1 phase of the cell cycle.

56. In its opposition Campbell states, and Strelchenko does not dispute in its reply (Paper 78), that several techniques were known in the art for culturing cells and separating cells into different phases of the cell cycle as of August 1995 (Paper 75 at 23 and Exh. 1081 at ¶¶19-23).

57. The '194 application states (Exh. 1008 at 5:14-28):

> In principle, the invention is applicable to all animals, including birds such as domestic fowl, amphibian species and fish species. In practice, however, it will be to non-human animals, especially non-human mammals, particularly placental mammals, that the greatest commercially useful applicability is presently envisaged. It is with ungulates, particularly economically important ungulates such as cattle, sheep, goats, water buffalo, camels, and pigs that the invention is likely to be most useful, both as a means for cloning animals and as a means for generating transgenic animals. It should also be noted that the invention is also likely to be applicable to other economically important animal species such as, for example, horses, llamas or rodents, e.g. rats or mice, or rabbits.

58. In the example section of the '194 application, bovine fibroblasts in the G0 phase of the cell cycle are used as donor cells. (Exh.1008 at 25:31-26:18).

59. Dr. Forsberg states that "it is unclear if the ('194) specification intends this to refer to true fibroblasts, or to 'fibroblast-like' cells that merely appear to look like fibroblasts in culture." since, according to Dr. Forsberg, the Campbell inventors have referred to the same cells as fibroblasts and fibroblast-like in a prior publication.[9] (Exh. 2030 at ¶ 13).

60. In a joint glossary submitted by the parties, fibroblasts are said to be "spindle shaped cells responsible for the formation of extracellular fibers such as collagen in connective tissues [footnote omitted]" (Paper 37 at 5).

The maintenance of correct ploidy:

61. Regarding the maintenance of correct ploidy, Dr. Forsberg testified as follows (Exh. 2030 at ¶ 21):

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[9] The publication Dr. Forsberg references is Wilmut et al, *Nature* 385:812-813 (1997). (Exh. 2013).

Furthermore, the claims currently pending in the '194 application all fail to include a step that the '194 applicants indicated was necessary for successfully practicing nuclear transfer; that is, the step of maintaining the diploid status of the transferred nucleus in conjunction with the activation step. For example, the '194 application (SX2002) describes the invention, as understood by the applicants, on page 5, lines 9-11, to include "subsequently activating the reconstituted embryo while maintaining correct ploidy. Even stronger language to this effect is found at page 14, lines 7-14:

> In the practice of the invention, correct ploidy must be maintained during activation. It is desirable to inhibit or stabilize microtubule polymerization in order to prevent or maintain correct ploidy. This can be achieved by the application of a microtubule inhibitor such as nocodazole at an effective concentration (such as about 5 μg/ml).

The '194 applicants, while stating that correct ploidy "must be maintained", have simply left this requirement out of the currently pending claims.

62. The '194 application states the following (Exh. 1008 at 2:31-3:2):

> ...we have shown that maintenance of correct ploidy during the first cell cycle of the reconstructed embryo is of major importance.

and (Exh. 1008 at 3:34-4:4):

> In reconstructed embryos correct ploidy can be maintained in one of two ways; firstly by transferring nuclei at a defined cell cycle stage, e.g. diploid nuclei of cells in G1, into metaphase II oocytes at the time of activation...

and (Exh. 1008 at 7:18-20):

Donors which are diploid at the time of transfer are necessary in order to maintain the correct ploidy of the reconstituted embryo; therefore donors may be either in the G1 phase or preferably,...in the G0 phase of the cell cycle.

and (Exh. 1008 at 19:30-20:6):
This protocol has a number of advantages over previously published methods of nuclear transfer:

1).....

2) Correct ploidy of the reconstituted embryo is maintained when G0/G1 nuclei are transferred....

Campbell preliminary motion 8

63. Campbell preliminary motion 8 under 37 CFR § 1.633(c)(1), seeks to redefine the interfering subject matter by substituting proposed count 5 for Counts 1 through 3.

64. Proposed count 5 is essentially a combination of Counts 1 through 3.

65. Proposed count 5 reads as follows (Paper 42 at 3)(emphasis in original):

A method according to any of claims 57 or 106 of Strelchenko application 09/357,445, wherein the ungulate animal is a **bovine, ovine, or porcine**, or a method according to any of claims 19, 23, 27, 31, 35, 39, 43, or 47 of Campbell application 09/650,195 [footnote omitted].

66. According to Campbell, it is appropriate to combine Counts 1 through 3 into one count since Counts 1 through 3 are not directed to inventions that are separately patentable from one another.

67. In particular, Campbell argues that neither its specification and claims, the Strelchenko specification and claims, nor the examiner treated the subject matter of Counts 1 through 3 as being separately patentable subject matter.

Campbell preliminary motion 4

68. Campbell moves to be accorded priority benefit of United Kingdom patent application GB 9517779.6 (Exh. 1023) ("the GB application"), filed 31 August 1995.

69. The disclosure of the GB application is substantially the same as the disclosure of the involved Campbell application.

70. Strelchenko argues that Campbell does not provide written description and enabling support for the subject matter of the count.

71. In its opposition 4, Strelchenko relies upon substantially the same arguments and evidence[10] Strelchenko relied upon to support its preliminary motion 3.

Campbell preliminary motion 5

72. Campbell argues that Strelchenko should not be accorded priority benefit of the filing date of its '851 application.

73. The '851 application states that the invention "comprises cloning animals by obtaining a non-embryonic cell from an animal to be cloned;

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[10] Strelchenko relies upon a second declaration by Dr. Forsberg. (Exh. 2039). In the second declaration, Dr. Forsberg expresses substantially the same opinions regarding the GB application as he did regarding the involved Campbell application.

reprogramming the cell to form a reprogrammed cell with the properties of an embryonic germ cell ('EG cell'); forming a cybrid by implanting the EG cell by nuclear transfer into an enucleated oocyte; and culturing the cybrid so as to generate an embryo." (Exh. 1020 at 5:15-18).

74. The '851 application defines embryonic germ cells as "PG [primordial germ cell] or other cells that have been reprogrammed to enter an immortalized totipotent state." (Exh. 1020 at 7:25-27).

75. Thus, the '851 application discloses a nuclear transfer cloning method where a totipotent cell is used as the donor cell.

III. Discussion

A. Campbell preliminary motions 1, 6, 7, and 9 under 37 CFR § 1.633(a)

All of the involved Strelchenko claims are barred under 35 USC § 135(b) and thus are unpatentable to Strelchenko. (FF[11] 16). Since the Strelchenko claims are unpatentable under 35 USC § 135(b), we need not and do not decide the Campbell 37 CFR § 1.633(a) preliminary motions attacking the patentability of the involved Strelchenko claims. Campbell preliminary motions 1, 6, 7, and 9 are DISMISSED as moot.

B. Strelchenko preliminary motion 4 and Campbell preliminary motion 2

Strelchenko preliminary motion 4 and Campbell preliminary motion 2 each seek the same relief, i.e., to add proposed claims 119 and 120 to the '445 application. If the proposed claims are added to the interference, then Strelchenko will have claims involved in the

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[11] Finding of fact.

interference that both parties agree are patentable to Strelchenko (Paper 60 at 15).[12] If, on the other hand, the proposed claims are not added to the '445 application, then Strelchenko will have no claims involved in the interference that are patentable to it.

Campbell and Strelchenko each filed its preliminary motion to add the proposed claims in response to an opponent's preliminary motion that is either dismissed or denied.[13] Ordinarily, it may be appropriate to dismiss Campbell preliminary motion 2 and Strelchenko preliminary motion 4 since the contingency which prompted each responsive motion did not come to pass.

Nonetheless, in the unusual circumstances before us, where Strelchenko has been left without patentable claims because of a decision in a separate interference, it may be appropriate to allow claims to be added to the involved Strelchenko application if the proposed claims: (1) interfere-in-fact with the Campbell claims, and (2) are patentable to Strelchenko.

Strelchenko recognizes that its proposed claims contain a "reprogramming step" that was not present in its claims that were designated as corresponding to the counts. According to

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[12] According to Campbell, "[t]he proposed claims are patentable to Strelchenko in that Campbell knows of no reason why the proposed claims, when properly construed, would be anticipated or obvious over the prior art" (Paper 29 at 10).

[13] Campbell indicated that its preliminary motion 2 is filed as a responsive motion under 37 CFR §1.633(i) in that Campbell wishes to add claims to the '445 application, in the event Strelchenko's preliminary motion 1 for a judgment of no-interference-in-fact is granted. (FF 24).

According to Strelchenko, its preliminary motion 4 is filed in response to Campbell preliminary motion 2 (to add proposed claims 119 and 120 to the '445 application) and preliminary motion 6 filed under 37 CFR § 1.633(a) for judgment that the Strelchenko involved claims are unpatentable to Strelchenko on the basis that the claims lack an enabling disclosure. (FF 26).

Strelchenko the reprogramming step "does not alter the scope of that step from the same corresponding step in involved claim 57 [14], as stated to the Examiner during prosecution" (Paper 60 at 9). In particular, Strelchenko states that "cultivation of the cells is the only exemplified method for the 'reprogramming step'" (Paper 60 at 12).

All claim interpretation begins with the language of the claims. The written description is available for clarification of the terms of the claims. *Robotic Vision Sys, Inc. v. View Eng'g, Inc.*, 189 F.3d 1370, 1375, 51 USPQ2d 1948, 1952 (Fed. Cir. 1999).

Proposed claims 119 reads as follows (FF 28):

> A method for preparing an ungulate animal, said method comprising:
> (a) obtaining a primordial germ cell from an ungulate fetus;
> (b) reprogramming said primordial germ cell to form a reprogrammed cell by cultivation in a culture medium;
> (c) forming a cybrid by nuclear transfer of said reprogrammed cell into an enucleated ungulate oocyte of the same species, wherein said oocyte is matured for about 16 to about 28 hours to form a first polar body prior to enucleation, and wherein said reprogrammed cell is a proliferating cell that is 12-15 μm in size;
> (d) activating said cybrid.

The reprogramming step is defined in the '445 disclosure as a step that converts a non-totipotent cell into a totipotent cell. (FF 32). Thus, the "reprogrammed" cell that acts as the donor cell in the method of claims 119 and 120 is a totipotent cell. (FF 41).

Campbell's claims use a donor cell that is a differentiated cell, such as a fibroblast. (FF 42). A differentiated cell is not a totipotent cell. (FF 43). Thus, a fundamental difference between Strelchenko's claims and Campbell's claims is that they use different types of donor

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[14] Claim 57 is contained in Counts 1 through 3. (FF 6 through 8).

cells for nuclear transfer. In particular, Strelchenko's claims require a totipotent donor cell while Campbell's claims require a donor cell that is not totipotent.

According to the '445 specification, a reprogramming step is undertaken such that a totipotent donor cell is used for nuclear transfer. (FFs 32, 35, 36, 38 through 41). It is not apparent to us, and Strelchenko has not sufficiently explained why, in view of its claims, it would have been obvious to use a non-totipotent donor cell for nuclear transfer. It is also not apparent to us, and Strelchenko has not sufficiently explained why, in view of Campbell's claims, it would have been obvious to include a reprogramming step to generate a totipotent donor cell when Campbell's claims specifically call for a differentiated donor cell.

We see no reason to add the proposed claims to Strelchenko's involved application at this time since the proposed claims do not interfere-in-fact with the involved Campbell claims. However, as an applicant, Strelchenko may pursue the proposed claims upon the resumption of ex parte prosecution before the examiner. We DENY Strelchenko preliminary motion 4 and Campbell preliminary motion 2 to add proposed claims 119 and 120 to the '445 application.

C. Strelchenko preliminary motion 3

Strelchenko moves for judgment that the Campbell involved claims are unpatentable under 35 USC § 112, ¶1, for lack of written description and lack of enablement.

In order to meet the written description requirement the specification must clearly convey to those skilled in the art that the applicant invented the claimed subject matter. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1562-63, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). "The written description requirement is found in 35 U.S.C. § 112 [¶1] and is separate from the enablement

requirement of that provision." *In re Wilder*, 736 F.2d 1516, 1520, 222 USPQ 369, 372 (Fed. Cir. 1984).

"The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent [application] coupled with information known in the art without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) . "The specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'." *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Strelchenko relies primarily upon the declaration testimony of Dr. Forsberg (Exh. 2030) to support its preliminary motion 3 (Paper 50 at 2).[15] We are unpersuaded by Dr. Forsberg's testimony for reasons set forth below.

Dr. Forsberg testified that the '194 application did not convey with reasonable clarity to those skilled in the art that the inventors were in possession of the claimed invention and did not disclose sufficient information to enable those skilled in the art to make and use the claimed invention. (Exh. 2030 at ¶ 26). A focus of Dr. Forsberg's testimony is his opinion that, given the '194 specification, a great deal of experimentation would have been needed to practice the subject matter of the '194 claims. However, Dr. Forsberg does not adequately explain why the amount of experimentation needed was unreasonable given the nature of the invention and the state of the art. "The test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in

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[15] In his testimony, Dr. Forsberg referred to a number of publications that are also cited as evidence in Strelchenko preliminary motion 3 (Paper 50 at 1-2).

question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed." *Ex parte Jackson*, 217 USPQ 804, 807 (BPAI 1982), cited with approval in *PPG Indus. Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996).

Dr. Forsberg testified that many of the Strelchenko claims are broad in scope. Breadth of the claims is a factor that we may consider in accessing the need for undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988); *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the Wands factors "are illustrative, not mandatory. What is relevant depends on the facts."). However, just pointing out that the claims are broad in scope, without more, is not sufficient to show that the claims lacked written description or an enabling disclosure. Dr. Forsberg does not explain sufficiently why the Campbell disclosure failed to provide, with reasonable specificity, how to make and use the full scope of the claims. While we are in agreement with Dr. Forsberg that the scope of many of the Strelchenko claims is quite broad, Strelchenko has the burden of proving that Campbell is not entitled to claims having such breadth.

Unpredictability is another factor we may consider in accessing whether undue experimentation is needed to practice the claimed invention. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. In an effort to demonstrate that the nuclear transfer method of cloning is unpredictable, Dr. Forsberg testified that others in the field have used various techniques to successfully clone pigs, rabbits, and mice. (Exh. 2030 at ¶¶ 18 through 20). However, neither

Dr. Forsberg's testimony nor Strelchenko's preliminary motion 3 specifically explains why cloning by nuclear transfer is unpredictable across the genus of non-human mammals. We understand from reading Dr. Forsberg's testimony and particularly his characterizations of successful efforts by others in the field, that cloning by nuclear transfer is a difficult, challenging, and inefficient[16] process. Dr. Forsberg's testimony leads us to believe that a considerable amount of experimentation would have been routinely undertaken when using the nuclear transfer cloning method. Dr. Forsberg's testimony does not persuade us that the amount of experimentation needed to practice the method of the '194 claims amounted to more than the amount of experimentation that would have been routinely undertaken by one skilled in the art.

Dr. Forsberg notes that the '194 application does not contain a working example using G1 cells. While the lack of a working example is another factor we may consider in evaluating enablement, *In re Wands*, id., the specification need not contain a working example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). Dr. Forsberg does not adequately explain why a working example was necessary to provide adequate written description and enabling support for involved Campbell claims.

We address below the specific arguments raised by Strelchenko in its preliminary motion 3 and the testimony of Dr. Forsberg as it relates to those arguments.

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[16] For example, one of the publications relied upon by Strelchenko reports that, in the case of "Dolly", nuclear transfer was undertaken in 434 oocytes resulting in only one live birth. Fulka et al., BioEssays 20:847-851, (1998). (Exh. 2029 (at 849)).

1. The failure of the '194 application to provide a time range for the period the reconstructed embryo is to be held without activation

The Campbell claims require "maintaining the reconstructed embryo without activation for a sufficient time to allow the reconstructed embryo to become capable of developing to term." (FFs 11 and 12) ("the non-activation time period limitation"). Strelchenko argues that the Campbell claims lack written descriptive support for the non-activation time period limitation because "the only way to identify the particular time period that is sufficient (except possibly in the case of bovines) is to perform the method and see if a particular fetus or mammal was obtained" (Paper 50 at 5). Strelchenko further argues that the Campbell claims were not enabled by the '194 specification since "the '194 application fails to teach those skilled in the art how to make and use the full scope of the claimed invention at the time of filing without undue experimentation" (Paper 50 at 22).

Regarding the non-activation time period limitation, Dr. Forsberg testified that (FF 49):

> The '194 application states that the purpose of this [non-activation time period limitation] requirement is to allow the donor nucleus to become exposed to the recipient cytoplasm. With regard to how this time period may be determined, the specification (SX2002) states at page 12, beginning at line 30:
>
> > The optimum period of time before activation varies from species to species and can readily be determined by experimentation. For cattle, a period of from 6 to 20 hours is appropriate. The time period should probably not be less than that which will allow chromosome formation, and it should not be so long either that the couplet activates spontaneously or, in extreme cases that it dies.

and that (FF 49) :

> Except for the time range given for cattle, no other time range is disclosed anywhere in the '194 application. Because there is not a single working example in the '194 application that demonstrates any successful cloning method in which a non-human mammalian cell in the G1 phase was used as the donor cell, there is also no example in the '194 specification where the time period described in the claims is shown to be correctly defined for the types of nuclear donor cells recited in the '194 application claims, either for bovines or for any other mammalian species.

Moreover, Dr. Forsberg testified that, given the low success rate in nuclear transfer cloning methods, "the only way to identify an appropriate time was by trial and error, with the hope that some time might ultimately succeed in producing the desired results (a fetus or live-born animal) despite repeated failures with precisely the same conditions." (FF 50). According to Dr. Forsberg, "[t]he amount of experimentation called for is enormous." (Exh. 2030 at ¶ 17).

Dr. Forsberg testified that there is no "working example" to show that the 6-20 hour time period is accurate "either for bovines or for any other mammalian species." (Exh. 2030 at ¶ 16). While the lack of a working example is a factor that we may consider in determining evaluating enablement, *In re Wands*, id., no example is needed if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, id. Dr. Forsberg's testimony does not explain sufficiently why an unreasonable mount of experimentation would be needed to arrive at a non-activation time period for practicing Campbell's claimed method in a cow or a bovine fetus, especially since a time of 6-20 hours "[f]or cattle" is set forth in the '194 specification. For example, Strelchenko has not directed us to evidence or a portion of Dr. Forsberg's testimony that sufficiently shows

that the time set forth in the '194 application for cows would not have been expected to produce the desired result.

As to the remaining Campbell claims (i.e., those not specifically directed to cows or bovines), Strelchenko has not shown why an undue amount of experimentation would have been needed to determine the appropriate non-activation time period, particularly in view of the guidance provided in the '194 specification. In contrast to Dr. Forsberg's statement that "there is virtually no guidance provided by the '194 application as to ... what might be an appropriate time that a reconstructed embryo, constructed using a G1 stage donor nucleus, should be maintained without activation..." (FF 51), the '194 specification states that an appropriate non-activation period time "can be readily determined by experimentation" and is a period that is long enough to allow for chromosome formation but not so long as to allow for spontaneous activation. Strelchenko's preliminary motion 3 does not adequately explain why the guidance provided in the '194 application would have been insufficient.

2. The '194 specification failed to provide sufficient written description of a non-human mammalian cell in the G1 phase

Campbell claims 35-50, directed to cloning a non-human mammal or fetus, require the step of inserting a nucleus of a donor cell that is in the G1 phase of the cell cycle. According to Strelchenko, Campbell was not in possession of the claimed method for cloning non-human mammals and fetuses since "there is not a single working example in the '194 application that demonstrates that a non-human mammalian cell in the G1 phase can be used a [sic-as a] donor cell in the claimed cloning method" (Paper 50 at 6). However, Strelchenko has not adequately

explained why the '194 application in not sufficient without the inclusion of a working example. *In re Borkowski*, id.

Strelchenko point to *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) for the proposition that "one skilled in the art may not be found to have been placed in possession of a genus or combination claimed at a later date in the prosecution of a patent application" where there is unpredictability in the art. However, the facts in *Smythe* differ significantly from those before us. In *Smythe*, the Board's decision affirming the examiner's rejection of the claims as lacking written description support was reversed even though Smythe's claims included a broader term than was present in its specification.[17] Strelchenko has not shown that Campbell's claims contain terms that are broader than those found in the '194 specification.

Strelchenko points to the following portion of the USPTO guidelines for written description (Paper 50 at 7) (66 Fed. Reg. 1099, 1106)[18] :

> When there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus... For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.

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[17] The Court indicated that the outcome may have been different if it had determined that there was unpredictability in performing the claimed method with species other than those specifically named. *Ire Smythe*, 480 F.2d at 1383, 178 USPQ at 284-85.

[18] "T]he Guidelines, like the Manual of Patent Examining Procedure ('MPEP'), are not binding, but may be given judicial notice to the extent they do not conflict with the statute." *Enzo Biochem. Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 964, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002).

The testimony of Dr. Forsberg and the other evidence Strelchenko has pointed out shows that cloning is a routinely difficult and inefficient process. It is not clear to us and Strelchenko has not explained, however, how Dr. Forsberg's testimony and the other evidence in its preliminary motion 3 show unpredictability such that the numerous species described by Campbell (see FF 57) are not sufficient to support Campbell's generic claims.

Regarding the donor cell limitation, Dr. Forsberg testified that (FF 53):

> There is not a single working example in the '194 application that demonstrates any successful nuclear transfer cloning method in which a non-human mammalian cell in the G1 phase was demonstrably used as the donor cell. No description is provided as to how one might obtain a uniform population of G1 cells, or any methods by which G1 cells might be identified from a population of cells in all cell cycle stages, much less that any such methods had actually been performed by the applicants prior to August 31, 1995 (the earliest possible filing date for the '194 application) or prior to August 30, 1996 (the date of which the PCT application from which the '194 application claims benefit).

While the lack of a working example may be considered in determining whether undue experimentation if required to practice the claimed invention, *In re Wands*, id., Strelchenko has not explained why a working example is necessary to provide written description support for Campbell's claims. While we agree that the Campbell claims are quite broad, the breadth of the claims alone is not enough to show that the Campbell claims lack written description support. It is Strelchenko's burden to show that Campbell was not in possession of the invention as claimed. Strelchenko has not met its burden.

3. The '194 specification does not sufficiently describe or enable a nuclear transfer cloning method that does not require diploidy to be maintained by some active step

According to Strelchenko, the original claim 1 of the '194 application required "activating the reconstituted embryo while maintaining correct ploidy" (Paper 50 at 8). However, none of the presently pending Campbell claims recite a step of maintaining correct ploidy of the reconstructed embryo during activation. Strelchenko argues that the '194 specification teaches that maintenance of the correct ploidy of the reconstructed embryo must be achieved by some active step and thus claims that lack a maintenance of correct ploidy step lack both written description and enablement support. In particular, Strelchenko argues that the '194 specification teaches that a microtubule inhibitor or stabilizer is needed to maintain ploidy (Paper 50 at 8-9).

Regarding the maintenance of ploidy, Dr. Forsberg testified as follows (FF 61):

> Furthermore, the claims currently pending in the '194 application all fail to include a step that the '194 applicants indicated was necessary for successfully practicing nuclear transfer; that is, the step of maintaining the diploid status of the transferred nucleus in conjunction with the activation step. For example, the '194 application (SX2002) describes the invention, as understood by the applicants, on page 5, lines 9-11, to include "subsequently activating the reconstituted embryo while maintaining correct ploidy. Even stronger language to this effect is found at page 14, lines 7-14:
>
> > In the practice of the invention, correct ploidy must be maintained during activation. It is desirable to inhibit or stabilize microtubule polymerization in order to prevent or maintain correct ploidy. This can be achieved by the application of a microtubule inhibitor such as nocodazole at an effective concentration (such as about 5 μg/ml).
>
> The '194 applicants, while stating that correct ploidy "must be maintained", have simply left this requirement out of the currently pending claims.

Regarding the maintenance of correct ploidy, the '194 application states the following (FF 62):

> ...we have shown that maintenance of correct ploidy during the first cell cycle of the reconstructed embryo is of major importance.

and:

> In reconstructed embryos correct ploidy can be maintained in one of two ways; firstly by transferring nuclei at a defined cell cycle stage, e.g. diploid nuclei of cells in G1, into metaphase II oocytes at the time of activation...

and:

> Donors which are diploid at the time of transfer are necessary in order to maintain the correct ploidy of the reconstituted embryo; therefore donors may be either in the G1 phase or preferably,...in the G0 phase of the cell cycle.

and:

> This protocol has a number of advantages over previously published methods of nuclear transfer:
> 1).....
> 2) Correct ploidy of the reconstituted embryo is maintained when G0/G1 nuclei are transferred....

We appreciate, based on what is stated in the '194 application and our own understanding of the art, that it is crucial to successful cloning that correct ploidy be maintained throughout the process. However, Strelchenko has not directed us to evidence demonstrating that correct ploidy is not maintained as stated and claimed in the '194 application claims, i.e., by transferring nuclei of cells in the G1 phase of the cell cycle into metaphase II oocytes. Strelchenko has not explained why Campbell would need to include a step of "maintaining correct ploidy" in its

involved claims when correct ploidy is inherently maintained by following steps recited in its claims.

Strelchenko argues that "the claimed requirement for a diploid cell in G1 as the nuclear donor cell is not the step by which ploidy is maintained" and that "[a]s seen the [sic-in the] original '194 application, ploidy maintenance requires a treatment that results in microtubule inhibition using nocodazole or microtubule stabilization using taxol" (Paper 50 at 9). However, neither the '194 specification nor the evidence pointed out to us by Strelchenko supports this argument.

As noted by Strelchenko, the '194 specification says that it is "desirable" to inhibit or stabilize microtubule polymerization to maintain correct ploidy. (FF 61). Thus our understanding from reading the '194 specification is that a microtubule inhibitor or stabilizer, such as nocodazole, would have been advantageous in performing the method claimed by Campbell, but not required. Strelchenko has not directed us to evidence that contradicts our understanding. In particular, Strelchenko has not directed us to evidence showing that the use of a microtubule inhibitor or stabilizer was necessary to achieve successful cloning.

4. The '194 specification does not sufficiently describe or enable the specific donor cell types in the G1 phase of the cell cycle

All the Campbell claims require that the donor cell be a cultured diploid differentiated cell, such as a fibroblast, in the G1 phase of the cell cycle ("the donor cell limitation"). According to Strelchenko, the '194 specification does not provide written description of or enablement for the donor cell limitation. In particular, Strelchenko argues that "while the individual words themselves can be found in different parts of the '194 application, there is no

reference direct or indirect to the complete claim limitation" (Paper 50 at 12) and that, despite the breadth of the Campbell claims, there is no guidance in the '194 application as to how to obtain the donor cells called for by the claims (Paper 50 at 16-20).

The following passages appear in the '194 application (FF 62):

> Donors which are diploid at the time of transfer are necessary in order to maintain the correct ploidy of the reconstituted embryo; therefore donors may be either in the G1 phase or preferably,...in the G0 phase of the cell cycle.

and (Exh. FF 54)

> The nuclei of quiescent G0 cells, like the nuclei of G1 cells, have a diploid DNA content; both of such diploid nuclei can be used in the present invention.
>
> Subject to the above, it is believed that there is no significant limitation on the cells that can be used in nuclear donors; fully or partially differentiated cells or undifferentiated cells can be used as can cells which are cultured *in vitro* or abstracted *ex vivo*.

and (FF 57):

> In principle, the invention is applicable to all animals, including birds such as domestic fowl, amphibian species and fish species. In practice, however, it will be to non-human animals, especially non-human mammals, particularly placental mammals, that the greatest commercially useful applicability is presently envisaged. It is with ungulates, particularly economically important ungulates such as cattle, sheep, goats, water buffalo, camels, and pigs that the invention is likely to be most useful, both as a means for cloning animals and as a means for generating transgenic animals. It should also be noted that the invention is also likely to be applicable to other economically important animal species such as, for example, horses, llamas or rodents, e.g. rats or mice, or rabbits.

In the example section of the '194 application, bovine fibroblasts in the G0, not G1, phase of the cell cycle are used as donor cells (FF 58).

a. written description

One skilled in the art reading the '194 specification would have been directed to use a donor cell that: (1) is in either the G0 or G1 phase of the cell cycle, (2) may be a cultured

differentiated cell, and (3) and may be from any animal, including a non-human mammal. Moreover, the '194 application uses fibroblasts as an example of a cell type which may be used in the disclosed method.

Strelchenko, citing *Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320,1326-1327, 56 USPQ2d 1481, 1486 (Fed. Cir. 2000),[19] argues that the '194 application does not have sufficient blaze marks to direct one skilled in the art to use cells in the G1 phase of the cell cycle for each type of mammal claimed (Paper 50 at 12-13).

In order to meet the written description requirement the specification must clearly convey to those skilled in the art that the applicant was in possession of the claimed subject matter. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1562, 19 USPQ2d at 1115. The specification must be considered as a whole when evaluating written description. *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1346, 54 USPQ2d 1915, 1918 (Fed. Cir. 2000).

Strelchenko has not convinced us, when we consider the '194 specification as a whole, that Campbell was not in possession of the invention as claimed. The '194 specification directs one to use either a cultured differentiated or undifferentiated donor cell, a non-human mammalian donor cell (with examples including cattle, sheep and pigs), and either a G0 or G1

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[19] *Purdue Pharma* cites *In re Ruschig*, 379 F.2d 990, 994-995,154 USPQ 118, 122 (CCPA 1967), which states:

> It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail or in finding one's way through the woods where the trails have disappeared-or have not yet been made, which is more like the case here-to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.

donor cell. A great deal of picking and choosing is not required to arrive at, e.g., a cultured differentiated bovine donor cell in the G1 phase of the cell cycle.

Strelchenko's arguments regarding Campbell's written description of a fibroblast, in particular, as the donor cell have some merit but are not sufficient to meet Strelchenko's burden of proof. The '194 specification specifically states that there is no significant limitation on what type of cell can be used as a donor cell. (FF 54). As Strelchenko points out, the '194 examples describe using fibroblasts in the G0 (and not G1) phase of the cell cycle (FF 58). However, it appears that fibroblasts are the only particular type of differentiated donor cell disclosed in the '194 specification. Strelchenko has not shown why one skilled in the art, choosing to use a differentiated G1 cell as the donor cell, would not have turned to the '194 examples for further guidance as to what particular type of differentiated cell to use.

b. Enablement

Strelchenko argues and Dr. Forsberg testified that the '194 application contains no teaching of how to isolate differentiated donor cells, such as fibroblasts, where the donor cell is in the G1 phase of the cell cycle. However, as noted by Campbell, and undisputed by Strelchenko in its reply (Paper 78), a number of techniques were known in the art for culturing and isolating cells in the G1 phase of the cell cycle as of Campbell's earliest filing date. (FF 56). "[A] specification need not disclose what is well known in the art." *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384-85, 231 USPQ 81, 94 (Fed. Cir. 1986).

Strelchenko argues that it is not clear what type of cells are intended by the term "fibroblast". According to Dr. Forsberg, "it is unclear if the ('194) specification intends this to refer to true fibroblasts, or to 'fibroblast-like' cells that merely appear to look like fibroblasts in

culture". According to Dr. Forsberg, the Campbell inventors have referred to the same cells as fibroblasts and fibroblast-like in a prior publication. (FF 59).

In a joint glossary submitted by the parties, fibroblasts are said to be "spindle shaped cells responsible for the formation of extracellular fibers such as collagen in connective tissues [footnote omitted]." (FF 60).[20] Claim terms are given their ordinary meaning unless there is sufficient reason to alter the meaning. K-*2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1363-1364, 52 USPQ2d 1001, 1005 (Fed. Cir. 1999). In the circumstances before us, we have not been persuaded that there is sufficient reason to alter the meaning of the term "fibroblast" as it appears in Campbell's involved claims. For example, Strelchenko has not shown that Campbell deliberately sought to alter the meaning by providing a definition of "fibroblast" that is different from its ordinary meaning. Moreover, Strelchenko has not shown that the term "fibroblast" is per se unclear or that the use of term "fibroblast" in the '194 claims makes the claims unclear.

Strelchenko's reason for stating that the term "fibroblast" is unclear in the '194 claims is that, according to Strelchenko, Campbell has used the term "fibroblast" and "fibroblast-like" to describe the same cells in another publication. However, Strelchenko has not explained to us why we should look outside the '194 specification to Campbell's other publications to define the term "fibroblast" and to define it in such a way as to make it unclear.

Nonetheless, even if we were to construe the term "fibroblast" as used in the Campbell claims to include something more than "true" fibroblasts, Strelchenko has not explained

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[20] The definition found in the joint glossary is consistent with Strelchenko's statement in its preliminary motion 3 that "[i]n the art, the term [fibroblast] formally refers to a mesodermally derived [cell] in the connective tissue and characterized in secreting fibrillar procollagen, fibronectin, and collagenase" (Paper 50 at 16).

sufficiently why the '194 claims lack enablement. Strelchenko has the burden of proof. Strelchenko cannot meet its burden simply by pointing to the breadth of the Campbell claims.

Strelchenko points out that the Campbell inventors acknowledged in a 1997 publication,[21] that they were unaware of the phenotype of the donor cell they used to produce the cloned sheep Dolly (Paper 50 at 17) and that it was not until several years after the '194 filing date that successful cloning using G1 donor cells was reported in a publication[22] (Paper 50 at 17-18). It is not apparent to us, and Strelchenko has not explained, how either publication shows that the '194 disclosure did not enable the '194 claims. For example, Strelchenko does not explain how either publication shows that G1 donor cells described in the '194 application would not have been expected to work in the nuclear transfer method of cloning claimed by Campbell.

5. The non-human mammalian recipient cells limitation

In a footnote, Strelchenko states that, "[i]n addition to the fact that the '194 application must enable all non-human mammalian donor cells for claims 39-50, the '194 [application] also must enable all non-human mammalian recipient cells" (Paper 50 at 21, fn. 2). However, Strelchenko has not directed us to any evidence indicating that the '194 application is not enabled for the recipient oocyte cells it claims.[23]

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21 Wilmut et al., *Nature* 385:812-812 (1997).

22 Kasinathan et al., *Nature Biotech.*, 19:1176-1178 (2001). (Exh. 2031).

23 Strelchenko's statement that "space limitations prohibit a full treatment here" does not excuse its failure to meet its burden of proof. If Strelchenko thought that circumstances warranted the authorization of additional pages for its preliminary motion, Strelchenko should have sought to file a motion under 37 CFR § 1.635.

D. Campbell preliminary motion 8

Campbell preliminary motion 8 under 37 CFR § 1.633(c)(1), seeks to redefine the interfering subject matter by substituting proposed count 5 for Counts 1 through 3.

Count 5 is essentially a combination of Counts 1 through 3. Proposed count 5 reads as follows (FF 65):

> A method according to any of claims 57 or 106 of Strelchenko application 09/357,445, wherein the ungulate animal is a **bovine, ovine, or porcine**, or a method according to any of claims 19, 23, 27, 31, 35, 39, 43, or 47 of Campbell application 09/650,195 [footnote omitted].

As the moving party, Campbell has the burden of explaining, *inter alia*, why the interfering subject matter should be redefined by substituting proposed count 5 for Counts 1 through 3. 37 CFR § 1.637(c). According to Campbell, it is appropriate to redefine the interfering subject matter by substituting proposed count 5 for Counts 1 through 3, since Counts 1 through 3 do not define separately patentable subject matter (Paper 42 at 4).

Campbell argues that neither the parties nor the examiner consider the cloning methods defined by Counts 1 through 3 to be separately patentable. In particular, Campbell argues that:

(1) the cloning methods claimed by Campbell and Strelchenko are identical for all species claimed (Paper 42 at 5-6).

(2) neither the Campbell nor the Strelchenko specification draws a distinction between the species of animals produced (Paper 42 at 5-6).

(3) the Campbell specification does not draw a distinction between the species of animals produced (Paper 42 at 5).

(4) in response to enablement rejections made during *ex parte* prosecution, Strelchenko argued that one skilled in the art would have a reasonable expectation of success in ungulates generally based on success in bovine and porcine animals (Paper 42 at 6).

(5) the examiner made no restriction requirement in either the Campbell or Strelchenko application during *ex parte* prosecution (Paper 42 at 7).

(6) the examiner rejected Strelchenko claims for obviousness-type double patenting on the basis that the species of Count 1 through 3 are not separately patentable over claims to methods of cloning "animals" and Strelchenko acquiesced to the rejection by filing terminal disclaimers (Paper 42 at 7-8).

In support of its position, Campbell relies upon :

(1) its assertion that the Campbell and Strelchenko specifications and claims do not treat the species of Counts 1 through 3 as being patentably distinct, and

(2) its assertion that, during *ex parte* prosecution, neither the examiner nor Strelchenko treated the species of Counts 1 through 3 as being patentably distinct .

Even if Campbell's assertions are correct, they do not provide evidence sufficient to show that the species of Counts 1 through 3 are not patentably distinct from one another.

Campbell's reliance on its own or Strelchenko's specification to show that the methods of Counts 1 through 3 are the same patentable invention is improper. It is the claims, and not the specifications, of each party that define the interfering subject matter and thus what is potential prior art to the other party. Thus it is the claims, not the specifications, that are available to show whether or not two inventions are separately patentable. *Noelle v. Lederman*,

http://www.uspto.gov/web/offices/dcom/bpai/its/104415-135.pdf, (BPAI 2001) (non-precedential).

Campbell notes that each party is claiming the same nuclear transfer method for use in bovine, ovine, and porcine animals, i.e., the animals of Counts 1 through 3, respectively. It is not apparent to us, and Campbell has not explained sufficiently, how the fact that a party claims the same method to produce different animals establishes that it was obvious to use the same method to produce each animal at the time the methods were invented.

Campbell argues that the examiner treated the species of Counts 1 through 3 as the same patentable invention by, e.g., failing to make restriction requirements.[24] Neither the panel nor Strelchenko is bound by the *ex parte* actions of the examiner. *Glaxo Wellcome Inc. v. Cabilly*, 56 USPQ2d 1983, 1984 (BPAI 2000). Nonetheless, it is our understanding that the examiner has discretion in deciding whether or not to require election between claims directed to separately patentable species. 37 CFR § 1.146. Thus, the examiner's failure to require an election of species does not establish that the examiner determined the subject matter of Counts 1 through 3 to be directed to the same patentable invention.

Strelchenko's actions during *ex parte* prosecution of its involved application as described by Campbell do not amount to sufficient evidence to show the claims to be separately patentable. We do not consider Strelchenko's filing of a terminal disclaimer necessarily to be an admission that the species of Counts 1 through 3 are directed to the same patentable invention. *Quad*

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[24] Where separately patentable species are claimed, it may be appropriate to require election of a single species for initial examination. 37 CFR § 1.146. A restriction requirement is appropriate where independent and distinct inventions are claimed. 37 CFR § 1.142.

Environmental Technologies Corp. v. Union Sanitary District, 946 F.2d 870, 874 20 USPQ2d 1392, 1394 (Fed. Cir. 1991).

Moreover, Strelchenko's statement during *ex parte* prosecution that "the successful use of the instantly claimed methods with both bovines and porcines would provide the ordinarily skilled artisan with the expectation that the instantly claimed methods could be successfully applied to ungulates generally" (Exh. 1014 at 7) does not seem to relate to whether Counts 1 through 3 define the same patentable invention. It is our understanding that Strelchenko's statement was made in an effort to rebut the examiner's position that Strelchenko was not enabled for the full scope of its claims. It is not apparent to us and Campbell has not adequately explained how Strelchenko's arguments that it was enabled for the full scope of its claim to cloning ungulates, establishes that the subject matter of Counts 1 through 3 (i.e., methods of cloning specific ungulates) are the same patentable invention.

Finally, Campbell argues that "[t]here is no evidence of record, and there is no reason known to Campbell" why the species found in Counts 1 through 3 would not be obvious in view of one another (Paper 42 at 9). It is Campbell who has the burden of proof in seeking to change the count. Campbell has not directed us to evidence, such as testimony or prior art, that establishes that Counts 1 through 3 are directed to the same patentable invention. The argument of counsel cannot take the place of evidence lacking in the record. *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 595, 44 USPQ2d 1610, 1615 (Fed. Cir. 1997). The counts set forth in the Notice Declaring Interference are presumed to be correct counts and it is Campbell's burden to rebut that presumption. Since Campbell has not met its burden, Campbell preliminary motion 8 is DENIED.

Redeclaration

While we do not adopt Campbell's proposed count, we will redeclare the interference to substitute Counts 4 through 6 for Counts 1 through 3. Counts 4 through 6 differ from Counts 1 through 3 in that:

(1) Counts 4 through 6 do not include any of the claims that are unpatentable to Strelchenko and,

(2) Counts 4 through 6 refer to Campbell's involved '194 application rather than Campbell's priority benefit application 08/803,165.

Count 4

A method according to claim 19 or claim 23 of Campbell application 08/650,194.

Count 5

A method according to claim 27 or claim 31 of Campbell application 08/650,194.

Count 6

A method according to claim 35, claim 39, claim 43, or claim 47 of Campbell application 08/650,194, where the "non-human mammal" is a pig or porcine and where the "non-human mammalian fetus" is a pig fetus or a porcine fetus.

E. Campbell preliminary motion 4

Campbell moves to be accorded priority benefit of United Kingdom patent application GB 9517779.6 ("the GB application), filed 31 August 1995 for Counts 1 through 3.[25] Counts 4

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[25] Campbell's preliminary motion 4 is unclear in that it also refers to Campbell proposed count 4. We understand Campbell to be moving for priority benefit as to **either** Counts 1 through 3 **or**, contingent on the granting of its preliminary motion to substitute Campbell

through 6 are substituted for Counts 1 through 3. Nonetheless, we consider the Campbell preliminary motion and the Strelchenko opposition to the extent they are relevant to whether Campbell should be given priority benefit of the GB application for the subject matter of Counts 4 through 6.

The GB application is substantially the same as Campbell's involved application. (FF 69). Campbell has shown where, in its GB application support is provided for each of its claims and thus the subject matter of Counts 4 through 6. (See Exh. 1031).

Strelchenko argues that the GB application does not provide written description or enabling support for the subject matter of the Counts. (FF 70). Strelchenko's arguments are substantially the same as the arguments it made in its preliminary motion 3. (FF 71). Strelchenko's arguments are unpersuasive here for the same reasons that they were unpersuasive in its preliminary motion 3. Moreover, some of Strelchenko's arguments, while appropriate in addressing whether Campbell's involved claims are patentable, are not appropriate in addressing whether Campbell is entitled to priority benefit of the GB application.

A single described enabled embodiment within the scope of the count is sufficient for priority benefit. *Hunt v. Treppschuh*, 523 F.2d 1386, 1389, 187 USPQ 426, 429 (CCPA 1975). However, Strelchenko argues that the GB application must provide written description and enablement for the full scope of its claims (that are part of the Counts) in order to be entitled to priority benefit (Paper 64 at 8, 11, and 22). While this may be true for patentability, only a single

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proposed count 4, Campbell proposed count 4 (see e.g., Paper 31 at 4).

constructive reduction to practice within the scope of the count is needed for priority benefit. *Cromlish v. D.Y.*, 57 USPQ2d 1318, 1319 (BPAI 2000).

Campbell preliminary motion 4 is GRANTED with respect to Counts 4 through 6.

F. Campbell preliminary motion 5

In its preliminary motion 5, Campbell moves to deny Strelchenko priority benefit of the filing date of its '851 application as to Counts 1 through 3. Both the Campbell preliminary motion and the Strelchenko opposition focus on whether the '851 application describes the subject matter of Strelchenko claim 57 or 106, which are part of Counts 1 through 3. However, Counts 4 through 6, which are substituted for Counts 1 through 3, do not include Strelchenko claim 57 or 106 and instead include only Campbell claims. Nonetheless, we consider the Campbell motion and the Strelchenko opposition to the extent they are relevant to whether Strelchenko should be given priority benefit of the '851 application for the subject matter of Counts 4 through 6.

The '851 disclosure must contain a single described and enabled embodiment within the scope of Counts 4 through 6 in order for Strelchenko to be accorded priority benefit of the '851 application. *Hunt v. Treppschuh*, 523 F.2d at 1389, 187 USPQ at 429 (CCPA 1975).

The nuclear transfer methods of Counts 4 through 6 require a donor cell that is a differentiated cell, such as a fibroblast. We do not see, and Strelchenko has not pointed out to us, where the '851 application describes a nuclear transfer method where a differentiated cell is used as the donor cell. Instead, the '851 application describes a method where a cell that is not totipotent, such as a differentiated cell, is reprogrammed to become a totipotent cell. It is this

totipotent cell that acts as the donor cell in the '851 method and not a differentiated cell as required by the Campbell claims. (FFs 73 through 75).

In its opposition, Strelchenko argues that the reprogramming step found in the nuclear transfer method described in the '851 application is present in its involved claims 57 and 106. However, claims 57 and 106 are not part of Counts 4 through 6.

We GRANT Campbell preliminary motion 5 with respect to Counts 4 through 6.

G. Strelchenko motion 2

In its motion 2, Strelchenko moves to be permitted to file a motion to declare an additional interference between its involved application and Campbell patents 6,147,276 and 6,252,122. Campbell does not oppose Strelchenko motion 2.

An interference may be declared if it is determined that there is interfering subject matter **claimed** by each party that is patentable to each party. See, e.g., 37 CFR § 1.606. Strelchenko does not have any patentable claims remaining in its involved application. Accordingly, there is no basis upon which to declare an additional interference. Strelchenko motion 2 is DENIED.

H. Campbell preliminary motion 10

Campbell moves to add claims 52 through 84 to its involved application. Campbell's motion is said to be responsive to Strelchenko's preliminary motion 3 filed under 37 CFR § 1.633(a). Since Strelchenko preliminary motion 3 is denied, we DISMISS Campbell preliminary motion 10 as moot.

I. Campbell preliminary motions 3, 11, and 12

Campbell preliminary motion 3 is contingent upon our granting the parties' preliminary motions to add proposed claims 119 and 120 to the '445 application. We deny the preliminary motions to add the claims. Thus, preliminary motion 3 is DISMISSED as moot.

Campbell preliminary motion 11 is contingent upon our granting Campbell's preliminary motion to add proposed claims 52 through 84 to its '194 application. We deny the preliminary motion to add the claims. Thus, Campbell preliminary motion 11 is DISMISSED as moot.

Campbell preliminary motion 12 is contingent upon our granting Campbell preliminary motion 11. Thus, preliminary motion 12 is DISMISSED as moot.

IV. Order

Upon consideration of the interference and for reasons given, it is

ORDERED that the interference is redeclared to the following extent:

A. The counts

The following counts, Counts 4 through 6, are substituted for Counts 1 through 3:

Count 4

A method according to claim 19 or claim 23 of Campbell application 08/650,194.

Count 5

A method according to claim 27 or claim 31 of Campbell application 08/650,194.

Count 6

A method according to claim 35, claim 39, claim 43, or claim 47 of Campbell application 08/650,194, where the "non-human mammal" is a pig or porcine and where the "non-human mammalian fetus" is a pig fetus or a porcine fetus.

B. Claim correspondence

The claims that were designated as corresponding to Count 1, are designated as corresponding to Count 4 (Paper 1 at 5).

The claims that were designated as corresponding to Count 2, are designated as corresponding to Count 5 (Paper 1 at 6).

The claims that were designated as corresponding to Count 3, are designated as corresponding to Count 6 (Paper 1 at 7).

C. Priority benefit

The parties are accorded the same priority benefit as in the Notice Declaring Interference (Paper 1 at 3-4), except for the following modifications:

Campbell is accorded priority benefit of its United Kingdom patent application GB 9517779.6, filed 31 August 1995 for each of Counts 4 through 6, and

Strelchenko is not accorded priority benefit of the filing date of its US application 08/812,851, filed 6 March 1997 as to any of Counts 4 through 6; and

FURTHER ORDERED that within **10 (ten) days** of the date of this ORDER, each party shall either: (1) file a statement indicating that it is relying on the preliminary statement it has already filed in the interference for the subject matter of Counts 4 through 6 or (2) file a new preliminary statement for the subject matter of Counts 4 through 6,

FURTHER ORDERED that Strelchenko motion 2 and Strelchenko preliminary motions 3 and 4 are DENIED,

FURTHER ORDERED that Campbell preliminary motions 2 and 8 are DENIED,

FURTHER ORDERED that Campbell preliminary motions 4 and 5 are GRANTED,

and

FURTHER ORDERED that Campbell preliminary motions 1, 3, 6, 7, and 9 through 12 are DISMISSED as moot.

RICHARD E. SCHAFER
Administrative Patent Judge

RICHARD TORCZON
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES

SALLY GARDNER LANE
Administrative Patent Judge

cc (via overnight carrier):

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